VOL. 30, NO. 1 JANUARY 1975

ood Drug Cosmetic Law
JOURNAL

Personal Criminal Liability Under the Federal Food, Drug, and Cosmetic Act
The Dotterweich Doctrine

. . . . . DANIEL F. O'KEEFE, JR.
. . . . . MARC H. SHAPIRO

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG LAW INSTITUTE, INC.

THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $25; single copies, $3. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

January, 1975

Volume 30 • Number 1

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . January, 1975

Volume 30 Number 1

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

This month's issue of the *Journal* is devoted to a discussion of the concepts of absolute and vicarious criminal liability of corporate officers for violations of the Federal Food, Drug, and Cosmetic Act. The statutory enforcement mechanisms provided in the Act are seizure, injunction, and criminal prosecution. Thus, the concepts of absolute and vicarious liability—firmly established in 1943 by the Supreme Court in the *United States v. Dotterweich* case—lie at the very heart of enforcement of this statute which affects the health and well-being of all Americans.

In the *Dotterweich* case, the Court interpreted the intent of Congress in enacting the 1938 Federal Food, Drug, and Cosmetic Act as holding "responsible" corporate officials, including presidents or other senior officers, personally criminally liable for violations of the Act though they had no wrongful intent and though they did not commit, authorize, or know of the acts which constituted the violations. The underlying rationale for this Congressional policy is that it provides the most effective means of assuring the highest possible standard of care in the manufacture and distribution of foods, drugs, and cosmetics.

Since 1943, the Government, and ultimately various federal courts, have applied the doctrine in different factual situations of importance to all students of food, drug, and cosmetic law.

The discussion in this paper is particularly timely now on the eve of Supreme Court review of *United States v. Park* in which the Fourth Circuit reversed the conviction of the president of a large food retailing corporation for violations of the Act occurring in one of the company's sixteen warehouses. This is the first litigated and reported case where a senior officer of a large corporation was convicted under the doctrine.

The purpose of the article is to shed light on the nature and scope of the *Dotterweich* doctrine for the education and information of those affected by it, and to place the doctrine into perspective in order to foster informed discussion of it among representatives of government, industry, academe, and consumers.

The authors set forth the legal limits to which the doctrine has been applied in litigated and reported cases since 1943; provide insight into the policies employed by government in bringing cases under the doctrine as well as recent government actions; and provide background and discussion of the basic policy pros and cons of the concept, including a discussion of the doctrine in light of general criminal jurisprudence. A major appendix to the paper examines the enforcement mechanisms of twenty-seven federal statutes related to health or safety, thus identifying enforcement alternatives to absolute and vicarious criminal liability and revealing Congressional trends in this area.

The paper will be helpful to practitioners by summarizing the current status of the doctrine at a time when the Court will again examine it. The opinion of the Court in the *Park* case, when rendered, will have more meaning to readers. The authors ask the Court for much needed guidance on the

proper instructions under the *Dotterweich* doctrine to be given to tryers of fact. The authors further suggest standards for the Court's consideration in the application of the doctrine.

The paper will also be of interest to those concerned with the Congressional policy underlying the doctrine by bringing together relevant material for consideration of that policy. The discussion by the authors of the basic rationale of the doctrine and the examination of countervailing arguments and alternatives is particularly helpful in this regard.

In a broader context, the examination in the paper of enforcement mechanisms employed by Congress in a variety of statutes will be helpful to a consideration of proper enforcement mechanisms to apply in any given legislative proposal, particularly in the regulation of health and safety matters.

The Food and Drug Law Institute is a nonprofit educational organization whose objective is to improve understanding of the nature and scope of laws and regulations applicable to the food, drug, cosmetic and related industries. Among its activities, the Institute sponsors food and drug law courses at several leading law schools, provides a fellowship program to assist worthy students in pursuing graduate law studies, publishes a series of books on food and drug law, sponsors various conferences of interest to those concerned with this area, and performs objective research on timely and important issues involving food, drug, and cosmetic law.

This article was prepared as part of the Institute's research efforts. It was authored by Daniel F. O'Keefe, Jr., President of The Food and Drug Law Institute and Marc H. Shapiro, a third year law student at the University of Virginia, who was employed by the Institute to perform basic research on this subject.

Vol. 30, No. 1 January, 1975

Food·Drug·Cosmetic Law
Journal

Personal Criminal Liability Under the Federal Food, Drug, and Cosmetic Act The Dotterweich Doctrine

By DANIEL F. O'KEEFE, JR. and MARC H. SHAPIRO

Mr. O'Keefe Is a Member of the Virginia and District of Columbia Bars. He Is President of The Food and Drug Law Institute and Wishes to Point Out That the Views Expressed in This Paper Are Those of the Authors and Are Not Necessarily the Views of The Food and Drug Law Institute.

Mr. Shapiro Is a Third-Year Law Student at the University of Virginia Law School. His Work on This Paper Was Performed While Employed as a Summer Law Clerk with The Food and Drug Law Institute.

I. The *Dotterweich* Doctrine

IN A 1943 FIVE-TO-FOUR DECISION, the United States Supreme Court held a corporate president personally criminally liable under the Federal Food, Drug, and Cosmetic Act[1] (hereinafter referred to as "the Act") for introducing into interstate commerce adulterated and misbranded drugs (1) even though there was no element of conscious fraud or awareness of wrongdoing on the president's part, (2) even though the president did not commit the violative acts, and (3) even though the president neither knew of, nor authorized, the acts which constituted a violation of law. The case was *United States v. Dotterweich.*[2]

For footnotes to text, see pages 44—49.

The *Dotterweich* case arose with a criminal prosecution under Section 303(a) of the Act against a corporation and an individual, its president and general manager, on three counts—one for shipping an adulterated drug and two for shipping a misbranded drug, both in interstate commerce.[3]

The alleged violations occurred when, in the course of its business, the defendant corporation, Buffalo Pharmacal Co., Inc., purchased drugs from a wholesale manufacturer and repackaged them for shipment to fill orders from out-of-state physicians. Two counts of violation of Section 502(a), which deems a drug or device misbranded if its labeling is false or misleading in any particular, were alleged. The first count charged that a drug was repackaged and shipped in interstate commerce under the corporation's label as "1000 Tablets Cascara Compound . . . (Hinkle)," followed by a list of ingredients, including strychnine sulphate. This particular ingredient, present in the tablets at issue, had been removed from the formula for the product stated in the National Formulary.[4]

The second count under Section 502(a) charged that the label on a bottle of digitalis represented the potency of the product to be twice what it was in fact found to be. These assertions of fact formed the basis for a third count alleging an adulteration violation of Section 501(c) which states that a drug is deemed adulterated if its strength differs from that which it purports or is represented to possess.[5]

As for Dotterweich, the individual defendant, it was shown that while he had no personal connection with either shipment, he was nevertheless in general charge of the corporation's business and had given general instructions to its employees, who did the actual repackaging, to fill orders received from physicians.[6] The plant constituted a small operation with twenty-six employees, all on one floor.[7]

The jury was instructed by the District Court for the Western District of New York as follows:

"Are you satisfied from the evidence that shipment[s] were made under his supervision by him as 'General Manager'? It is not necessary for the Government to prove that he personally and physically made the shipment himself. It is sufficient if the evidence establishes to your satisfaction that it was made under authority conferred by him as general manager upon his subordinates. . . ."[8]

The jury verdict acquitted the corporation but found Dotterweich guilty on all three counts. A fine of $500 on each count was

For footnotes to text, see pages 44—49.

imposed, with payment suspended on the second and third counts. In addition, a sixty-day probation on each count, to run concurrently, was imposed.[9]

Appeal was taken to the Second Circuit in *United States v. Buffalo Pharmacal Co.*,[10] which reversed Dotterweich's conviction on the technical grounds that he was not a "person" within the meaning of the Act.[11]

The Supreme Court, in a 5-4 decision, reversed the Court of Appeals and reinstated Dotterweich's conviction.[12] Holding Dotterweich was a "person" within the meaning of the Act,[13] Justice Frankfurter, speaking for the majority, said:

"Such legislation [legislation like the Food, Drug, and Cosmetic Act 'whereby penalties serve as effective means of regulation'] dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. . . . And so it is clear that shipments like those now in issue are 'punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares'. . . ."[14]

The burden of acting was thus placed on persons otherwise innocent but standing "in responsible relation to a public danger" and the occurrence of the prohibited act is sufficient, without any element of "awareness of wrongdoing," to bring into play the criminal sanctions of the statute insofar as a "responsible" party is concerned.

The Court went on to state:

"under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. *The offense is committed,* unless the enterprise which they are serving enjoys the immunity of a guaranty, *by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws.* . . ."[15] (Emphasis added)

Thus, having found that the statute prohibits the introduction into commerce of misbranded or adulterated articles by a "person," having found Dotterweich a "person" within the meaning of the Act, having found that the statute dispenses with the conventional requirement of awareness of some wrongdoing for criminal conduct, and the jury having found Dotterweich "responsible," the Court upheld his conviction.

For footnotes to text, see pages 44—49.

"Hardship," the Court said,

"there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."[16]

Commenting on the criteria for establishing which class of employees stand in a "responsible" relationship so as to be held so liable, the Court stated that an attempt to define such criteria would be "too treacherous," noting simply that such matters must be entrusted to "the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries. . . ."[17]

Justice Murphy, in his dissent, stated:

"There is no evidence in this case of any personal guilt on the part of the respondent. There is no proof or claim that he ever knew of the introduction into commerce of the adulterated drugs in question, much less that he actively participated in their introduction. Guilt is imputed to the respondent solely on the basis of his authority and responsibility as president and general manager of the corporation."[18]

Thus, the first principle set forth by the case was that the distribution of adulterated or misbranded drugs in violation of the Federal Food, Drug, and Cosmetic Act is a crime not requiring any conscious fraud or awareness of wrongdoing. The doing of the prohibited act is sufficient. The concept of absolute liability was thus firmly established. The second principle set forth in the case was that a corporate official may be held personally and criminally liable if he has "a responsible share in the furtherance of the [violative] transaction . . ." even though he did not commit the act or know of its commission. Thus, the concept of vicarious liability became established, holding a corporate official personally criminally responsible in certain circumstances for the acts of his employees which he did not know of or authorize. Simply put, that is the *Dotterweich* Doctrine.

II. The Purpose of This Paper

The *Dotterweich* case raises many questions concerning the scope and manner of its application. For example, does it apply to products other than drugs? Is it limited to violations involving public health and safety? Further, the Court refused to define which classes of employees stand in a "responsible" relationship to an illicit act. Is it sufficient to show that a defendant holds the title of president of a

For footnotes to text, see pages 44—49.

corporation? Is it sufficient to show that a president exercises general overall authority over the corporation? Is it necessary to show that a defendant bears some relationship to the specific operation or plant which causes the violative acts? Is it necessary to show that a defendant bears some relationship to the specific acts which resulted in violation? How has the government sought to apply the doctrine?

Also, questions of public policy are raised. Are the concepts of absolute and vicarious criminal liability in the public interest? Are these concepts unique in our criminal jurisprudence? What enforcement mechanisms are employed in other federal health- and safety-related statutes?

The purpose of this paper is to shed light on the nature and scope of the *Dotterweich* Doctrine for the education and information of those affected by it, and to place the doctrine in perspective in order to foster informed discussion of it among representatives of government, industry, academe, and consumers. We will seek (1) to define the legal limits to which the doctrine in fact has been applied in litigated and reported cases since 1943 (including a discussion of the very recent case of *United States v. Park*,[19] in which the Fourth Circuit may have placed new limits on the *Dotterweich* Doctrine as it has been interpreted over the years); (2) to provide insight into the policies employed by the government in bringing cases under the doctrine; (3) to provide insight into recent government actions under the doctrine; and (4) to provide background and a discussion of the basic policy pros and cons of the concepts of absolute and vicarious criminal liability under the Act.

Our purpose is not to take either "side" of the issue, but rather to set forth relevant analysis in order to foster informed discussion. Also, in our discussion, we will not inquire *per se* into questions of whether the Court properly interpreted the intent of the Federal Food, Drug, and Cosmetic Act, or whether the Court might now reexamine the basic doctrine on constitutional or other grounds.[19a]

III. Litigated and Reported Cases

Since 1943, when *Dotterweich* was decided, there have been before the courts a series of situations in which the *Dotterweich* Doctrine has been applied. A review of these cases is essential to understand the impact the doctrine has today.

For footnotes to text, see pages 44—49.

In this section we will examine individually, major reported cases involving the doctrine, and then summarize the scope of the doctrine today as reflected in the reported cases. Unfortunately, in some cases—particularly older ones where records no longer exist—information which would be useful was unavailable.

A. Analysis of Cases

A case decided shortly before *Dotterweich, United States v. Greenbaum,*[20] held a corporate president of a bakery criminally liable for introducing in interstate commerce, cans of rotten eggs in violation of Section 402(a)(3), which provides that a food shall be deemed adulterated "if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. . . ." Defendant moved to dismiss the information and for a directed verdict on the grounds that the information failed to charge a crime in that it failed to allege that the defendant knew the eggs were rotten when he shipped them and since no proof of such knowledge was offered.

The Third Circuit upheld the conviction, finding that knowledge and wilfulness are not statutory elements of the crime, and interpreting the Act as not requiring knowledge, particularly since Section 305,

"a preliminary requisite to prosecution, is designed to search out the possible innocent mind of the particular offender by establishing before trial, his good faith or the extent of his actual knowledge and wilfulness."[21]

The defendant was sentenced to three months in prison and a fine of $300 was imposed. The extent of Greenbaum's actual participation in the acts or the business is not clear, but it is interesting to note that in this case a defendant was *sentenced to prison* without proof of *scienter.*[22]

Subsequently, *Dotterweich* held that failure to provide a Section 305 hearing was not a statutory bar to prosecution in the factual situation there presented.[23]

In *United States v. Parfait Powder Puff Co.,*[24] a corporate defendant was convicted for introducing into interstate commerce, hair lacquer pads which contained a deleterious substance and therefore were adulterated in violation of Section 601(a), under which a cosmetic is deemed adulterated "if it bears or contains any poisonous or deleterious substance which may render it injurious to users. . . ."

For footnotes to text, see pages 44—49.

The facts of the case show that the defendant company contracted with a second company whereby the second company manufactured, packed and distributed the cosmetic to defendant's customers, shipping it according to defendant's instructions and under its label. Without the defendant's knowledge, the second company substituted the deleterious substance. As soon as the defendant learned of the substitution, it forbade use of it.

Defendant's conviction was upheld, the court finding the defendant responsible for the acts of his delegate where the defendant is the moving force in the introduction of the article into interstate commerce on his behalf, whether or not the defendant knew of the violation.

The case suggests that a person can be held vicariously responsible for the acts of his delegate where the delegate fails to meet the legal requirements of the statute even though the person did not know of these acts. The court said:

"The person who brings goods into commerce, by whatever means or implements, is bound to see that the commodity thus put into commerce is not beyond the pale of the legislative act."[25]

While the court uses the word "person," and while this case frequently has been cited for the proposition of absolute and vicarious liability under the Act, there was no individual defendant in this case.

In *Kordel v. United States*,[26] an individual defendant was found guilty of a misbranding violation under Section 502(a), prohibiting false and misleading labeling, and Section 502(f), requiring adequate directions for use. The defendant, who produced and marketed health products, claimed to be an expert on nutrition. The alleged violation occurred when pamphlets he had written, which he claimed were scientific publications, were shipped separately to the same consignee and destination to which the drugs had been shipped earlier. The pamphlets contained statements concerning the efficacy of the products which were found to be false and misleading. Contrary to defendant's claim that the pamphlets were merely scientific opinion,[27] the government argued that the pamphlets constituted labeling. The Supreme Court, in a 5-4 decision, agreed and affirmed the conviction, which fined defendants a total of $4,000.

In this case, while the defendant certainly was aware of his conduct, he may have been unaware that his conduct violated the law, believing the pamphlets more likely to be classified as scientific

For footnotes to text, see pages 44—49.

literature or permissible advertising, rather than "labeling" under the Act. However, it was not incumbent upon the government to prove wrongful intent under the *Dotterweich* Doctrine.

The case raises the question of the fairness of criminal conviction for conduct not clearly unlawful when the acts are committed and where scientific judgments may differ.[28] The four dissenting Justices appeared concerned about the first point,[29] but the outcome may have been colored by the facts of the case. As the Seventh Circuit opinion said:

"All [government expert medical witnesses] were agreed that while the claims were absurd and fantastic, they were dangerous in that they tended to lull people into a false sense of security in reliance on the drugs when they might need professional diagnosis and treatment. . . ."[30]

Similarly, in *United States v. Kaadt,*[31] defendants who ran a diabetic clinic were held criminally liable for shipping a drug in interstate commerce accompanied by certain printed material which was determined to constitute false and misleading labeling in violation of Section 502(a) by creating the impression that the drug would be efficacious in the cure, mitigation and treatment of diabetes whereas in fact it was not. The defendants argued that at issue was an honest difference of medical opinion. However, the court found that there was sufficient competent medical evidence for a jury to decide that the labeling was false and misleading.

The jury had been instructed, according to the Seventh Circuit's opinion, that:

"if they found that any or all of the defendants shared responsibility in conducting the business and that the operation of that business resulted in unlawful distribution of misbranded drugs, the defendants who shared such responsibility might be found guilty. . . . [The jury] in determining whether the defendants did have a responsible share in the conduct of the business . . . must take into consideration the work that each defendant did at the Kaadt Diabetic Clinic or Institute, the duties and responsibilities of each, and the extent to which each controlled or directed the conduct of the business."[32]

In short, while the extent of personal involvement of each of the defendants is unknown, the jury was told that if a defendant shared responsibility for the *conduct of the business,* regardless of whether he physically participated in the introduction of the misbranded drugs into interstate commerce, he could be held liable.

Again, the result in this case of criminal conviction and prison terms for defendants in a situation which might have been construed to constitute honest differences of medical opinion probably was

For footnotes to text, see pages 44—49.

colored by the facts of the case. For, as the trial judge said to defendants at sentencing:

"I am satisfied that for many years you have engaged on a wide scale in a sordid, an evil and a vicious enterprise without the slightest regard or consideration for the patients that consult you. . . ."

Also, he said:

"in their avarice and greed for wealth they wrongfully advised these trustful patients, and, as a result, they suffered permanent damage and injury, and some have gone to an early grave."[33]

In a frequently noted case, *Golden Grain Macaroni Co. v. United States,*[34] the president of the corporation (also general manager of its plant) was found personally criminally liable although he was absent from the plant during the time the violation occurred. Here, macaroni permeated with insect parts was held to be adulterated. The defendant was tried without a jury, found guilty and fined $5,000. The defendant argued that he could not be held responsible because he was absent from the plant during the period in which the food was shipped; because he was absent when the evidence was obtained; and because he did everything within his power to ensure that the factory would be in a sanitary condition both before and during his absence. Defendant contended that he had issued instructions which, if carried out, would have prevented the insanitary conditions.[35] The Ninth Circuit responded that some of the products were manufactured and packed before he left, that insanitary conditions had prevailed for a considerable length of time prior to his departure, and that he and the corporation had suffered a previous conviction for like violations. It should also be noted that, as general manager, the defendant was in charge of the facility.

The court may have held him criminally responsible by imputing knowledge to him of the plant conditions. This theory of liability in this case is reinforced by the court statement that:

"it is unnecessary to rest decision in this respect on the settled rule appealed to by government counsel that the criminal responsibility of a corporate officer having broad authority such as that possessed by this defendant does not depend upon his physical presence."[36]

In *United States v. H. Wool & Sons, Inc.,*[37] a corporation and its secretary were held criminally liable for a misbranding violation. The corporation, a wholesaler of dairy products, repackaged butter held for sale and falsely labeled it in violation of Section 301(k) as weighing one pound when in fact it weighed less.

For footnotes to text, see pages 44—49.

Defendants contended they had no knowledge of the out-of-state origin of the butter or that the repackaged butter was underweight. Citing *Dotterweich,* the court held that it was unnecessary to prove that defendants knew of these facts and affirmed the convictions of both the corporation and individual defendant.

Though the court did not specifically address the issue of the individual defendant's "responsibility," in another context it noted that:

"the dividing line between Herbert Wool and the Corporation was at best a shadowy one. The Company was a family-owned enterprise. . . . Wool's testimony makes it quite apparent that he was the dominating factor in the enterprise and that he was intimately concerned in its affairs."[38]

That intimate concern was more sharply brought into focus by the government brief before the Second Circuit which points out that the jury had found that Wool was the general manager and was responsible for all the activities of the corporation, specifically including the activities of the butter printing room where the butter was packaged and labeled. He also shared in the buying of the butter.[39] While those facts do not directly show that he knew of the underweight state of the butter, the corporation had suffered previous fines for short weight. Wool was fined $1,000 and sentenced to six months in jail.[40]

In *Wool,* therefore, lack of knowledge of violation was again held irrelevant to criminal conviction of an individual; however, in this instance, the violation was clearly economic, affecting the consumer by shortchanging his pocketbook, but representing no health or safety hazard—and the defendant was sentenced to jail. While the "responsibility" of the individual defendant was not discussed by the court in the context of this paper, it was reasonably clear that Wool was fairly close to the situation resulting in the misbranding.

In *United States v. Diamond State Poultry Co.,*[41] a corporation and its two major officers were convicted of introducing into interstate commerce chicken found to be decomposed and diseased and therefore adulterated in violation of Section 402. Each individual was given a three-year probation and the corporation was fined $1,000.[42]

In response to the individual defendants' contention that they did not aid and abet and were not criminally responsible for the shipments, the trial court noted that:

"Evidence is clear defendants Howard and David Polin were responsible for the operation of . . . [the corporation. Defendant David Polin stated at a Section 305 hearing that] he had instructed his employees to be careful in

For footnotes to text, see pages 44—49.

grading poultry and on occasions opened crates to see if his instructions were followed. Defendant Howard Polin stated he periodically checked condition of shipped poultry. . . . [The individual] defendants made policy for defendant . . . [corporation]. Individual defendants were the two major officers of the corporate defendant. . . ."[43]

Citing *Dotterweich, Greenbaum* and *Parfait Powder Puff,* the court further stated:

"Under the Food, Drug, and Cosmetic Act, proof of personal participation of an individual defendant is not required to establish guilt if the individual is the responsible person for the operation of the business out of which the violation grows."[44]

While the court cites as the rule of law that the person responsible for the operation of the business can be held liable, the facts of the case clearly indicate that the individual defendants, while they may not have personally inspected the chickens in question, did inspect chickens on occasion and were otherwise intimately involved with the operations. Another interesting point in the case is that one of the individual defendants contended that he instructed his employees to be careful in grading poultry and, on occasion, opened crates to see if his instructions were followed. This contention of "due care" on behalf of defendants was not discussed by the court. It is not clear whether the court was unconvinced of the facts or rejected the argument as irrelevant.

In the most recent affirmation by the Supreme Court that a violation can occur without a wrongful intent, *United States v. Wiesenfeld Warehouse Co.,*[45] the Court reversed a District Court dismissal of a criminal information. The Supreme Court ruled that a public storage warehousing company, if it held food under insanitary conditions between interstate shipment and ultimate sale, could violate Section 301(k) which prohibits the doing of any act with respect to a food held for sale after interstate shipment which results in such article being adulterated or misbranded.

While there was no individual defendant in the case, the matter of criminal intent was discussed. The Court stated that:

"It is settled law in the area of food and drug regulation that a guilty intent is not *always* a prerequisite to the imposition of criminal sanctions. Food and drug legislation, concerned as it is with protecting the lives and health of human beings, under circumstances in which they might be unable to protect themselves, *often* 'dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. . . .'"[46] (Emphasis added)

The use of the emphasized words by the Court *may* indicate a concern about the concepts of absolute and vicarious liability, at least

For footnotes to text, see pages 44—49.

permitting consideration of a defense of due care. In this regard, Justice Stewart's suggestion in his opinion is most interesting:

"It is argued . . . that the Government in this case is seeking to impose criminal sanctions upon one 'who is, by the very nature of his business, powerless' to protect against this kind of contamination, however high the standard of care exercised. Whatever the truth of this claim, it involves factual proof to be raised defensively at a trial on the merits."[47]

While a possible defense of due care has not evolved into a legal doctrine, it may become such and the argument may well have some practical effect also. For example, if at a preliminary Section 305 hearing, an individual can show (1) an appropriately high standard of care and (2) facts and circumstances that made the violation impossible or difficult to avoid, it is possible that an administrative decision not to prosecute would be made by the Food and Drug Administration (hereinafter FDA) or the Department of Justice.

In *United States v. Shapiro,*[48] the Sixth Circuit affirmed the District Court's revocation of defendant's probation and the imposition of a six-month sentence. The defendant, owner of a cookie factory, had earlier pled guilty to a violation of Section 301(a) and (k) and had received a fine and a two-year sentence probated on the condition that he conduct his food handling in accordance with the Federal Food, Drug, and Cosmetic Act. A subsequent FDA inspection of the premises found them to be in noncompliance with FDA regulations in that they were accessible to, and infested with, vermin. As a result, the revocation of probation and sentencing followed.

The defendant argued that he was no longer a responsible officer of the company. Before the inspection, the defendant had entered into a formal agreement to sell the business to a third party, although the final closing did not occur until three days after the inspection. The agreement gave the "operations and management" to the third party approximately two weeks before the inspection. Thus, the defendant argued, equitable title, and therefore responsibility, had passed from him before the FDA inspection.

In rejecting this argument, the Sixth Circuit noted that Shapiro had made several visits to the plant after the "operations and management" agreement and had adequate opportunity to observe the conditions. The court also noted that the results of the FDA inspection showed a continuing lack of interest in plant sanitation. The court said:

"Here Shapiro held the same corporate title on the date of the inspection that he held on the date he entered the guilty pleas to violating the Act. During that period his ownership of the corporate assets actually increased from

For footnotes to text, see pages 44—49.

50% to 100%. In his capacity as president of the company and owner of all the assets, Shapiro had the power and authority to devise whatever measures were necessary to assure compliance with the FDA regulations. There was no need for him to continue producing cookies under unsanitary conditions. He could have shut down the plant until the company was sold and new ownership could assume complete and unobstructed control. He could have required Red River [the third party] . . . to assure that adulterated food products from the Tasty plant would not be made available to the consumer. Or he could have completely and adequately cleaned the plant. It is clear that appellant failed to implement adequate safeguards at any time."[49]

This case represents another affirmation of the principle that neither physical presence nor personal participation is necessary for a finding of criminal responsibility under the Act. The case also suggests the principle that in some situations a man divested of control might still be held responsible.

Finally, there is the case of *United States v. H. B. Gregory Co.*,[50] where a bakery supply warehouse which supplied ingredients to bakeries throughout Milwaukee was found to have a rodent problem whereby food became adulterated in violation of Section 301(k). Generally, the adulteration allegedly occurred when rodent excreta pellets and urine stains were found in and around the food.

The individual defendant, James H. Gregory, president and treasurer of the firm, told the FDA inspector that he was in charge of the sanitation program and, specifically, of the rodent control program in the warehouse, and that he was there on a daily basis. The Seventh Circuit affirmed the trial court, which had fined Gregory $500 on each of four counts.

Finding that Gregory "had personal responsibility for all operations of the warehouse," the Court of Appeals said:

"Mr. Gregory was a person in a position of sufficient authority and responsibility in the conduct of the business . . . to be held personally and strictly liable for violations of the Act committed in the course of such corporate business."[51]

The court further stated:

"Mr. Gregory seeks to undermine the *Dotterweich* standards and cites certain state court cases and scholarly writings challenging the lack of a *scienter* requirement in criminal cases, and here in particular because the standard fails to require a *causal relation* between the individual and the violation of the Act. (Emphasis added)."[52]

The court concluded:

"If the Supreme Court standards of individual criminal liability announced in *Balint, Dotterweich,* and *Wiesenfeld Warehouse, supra,* are to be set aside, we shall defer to the Court's collective wisdom in that area. We shall not undertake to overrule the Supreme Court."[53]

For footnotes to text, see pages 44—49.

Thus, as recently as March of 1974 when the *Gregory* case was decided, a Court of Appeals followed *Dotterweich,* but again in a context where the individual defendant apparently was close to the operation in which the violation occurred.

B. Summary of Case Analysis

Dotterweich made it crystal clear that drug manufacturers are to be held responsible for the integrity of their products under a statute which punishes the act of introducing, or delivering for introduction into interstate commerce, a misbranded or adulterated drug. The burden is placed on the manufacturer and conscious fraud or awareness of wrongdoing are not relevant to criminal conviction where a prohibited act occurs. Thus, the Federal Food, Drug, and Cosmetic Act imposes an *absolute liability* upon drug manufacturers.

Also, *Dotterweich* made it clear that "responsible" corporate officials could be criminally convicted under the Act even though they did not commit, know of, or authorize the commission of the violative act. Thus, the Act also imposes a *vicarious liability* upon "responsible" persons for acts committed by others.

Since 1943 when *Dotterweich* was decided, individual defendants have been criminally convicted and the concepts of both absolute and vicarious liability have been applied in cases charging violations not only of the sections of the Act relating to drugs,[54] but also to sections relating to foods.[55] The doctrine also has been followed in a criminal case involving cosmetics, although no individual defendant was a party in that case.[56] And, while most cases have involved charges of misbranding or adulteration related to public health or safety, at least one case involved solely economic misbranding—short-weighted butter—bearing no health or safety risk to the public.[57] Theoretically, at least, it appears that both facets of the doctrine apply to *any* violation of the Act.

The doctrine has been applied not only to those manufacturing and distributing products, as in *Dotterweich,* but also to wholesalers,[58] retailers,[59] and warehouse operators.[60] The doctrine has been applied not only to corporate officers, but also to partners.[61] Thus, it appears that any "responsible" person under the Act is subject to absolute and vicarious liability.

Jail sentences,[62] terms of probation,[63] and criminal fines have been imposed,[64] all without the necessity of proof of *scienter,* and in

For footnotes to text, see pages 44—49.

situations where persons other than the convicted defendant performed the violative acts. In one case, a jail sentence was imposed although the offense charged related to economic misbranding, without risk to public health or safety.[65] In another case, the court ruled that intent was not a necessary element, even for conviction of a felony under the Act.[66]

It should be noted, however, that jail sentences have been relatively rare and fines levied generally have been small in amount. It should also be noted that, in many cases, there were facts presented as to the personal culpability of the defendant which may have influenced trial judges and juries, although as a matter of law, awareness of wrongdoing was not necessary to prove. Thus the doctrine has come to affect those cases where the individual may have been personally knowledgeable and culpable, for even in those instances there has been no burden of proof on the government, thus making the task of prosecution easier.

The *Kaadt* case applied the doctrine, and individuals were sentenced to prison, in a situation where the acts resulting in violation were not clearly violative of law at the time of their commission and where there might be an argument of honest difference of scientific judgment. However, the facts of the case could well have affected the result.

It also has been held that failure to hold a Section 305 hearing is not a statutory bar to prosecution.[67]

Thus, the legal limits of the doctrine are quite broad in spite of the recent Supreme Court dictum in *Wiesenfeld Warehouse* indicating that the Court might consider a defense of due care.

The most difficult concept to define is the question of the test of "responsibility" and its application. The test set forth in *Dotterweich* is that the offense is committed by "all persons who aid and abet its commission," by all who share "responsibility in the business process resulting in unlawful distribution," and "by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws."

An individual need not have any criminal intent, need not personally commit a violative act, or know of it, or be physically present in order to be held liable, if he is "responsible" under the *Dotterweich* test.

For footnotes to text, see pages 44—49.

There are some dicta to the effect that a corporate president may be held absolutely and vicariously liable solely on the basis of his general authority and responsibility as president for the overall operation and conduct of the business. For example, Justice Murphy's dissenting opinion in *Dotterweich* said: "guilt is imputed to . . . [Dotterweich] solely on the basis of his authority and responsibility as president and general manager of the corporation."[68] And, the District Court in *Diamond State Poultry Co.*, said that "proof of personal participation of an individual defendant is not required to establish guilt if the individual is the *responsible person for the operation of the business* out of which the violation grows." (Emphasis added.)[69] Also, in *Gregory,* the Seventh Circuit said that the individual defendant "was a person in a position of sufficient authority and responsibility *in the conduct of the business* . . . to be held personally and strictly liable. . . ." (Emphasis added.)[70]

However, the factual situations in the cases do not go that far. In all cases analyzed thus far for which we have sufficient facts, convicted individual defendants have always in fact had a closer connection to the operation in which the violation occurred than the mere holding of the title of president or possession of the general authority for the general conduct of the business. The facts in these cases do not suggest that defendants must actually perform a violative act or be present during its commission. However, *close and immediate supervisory control by the defendant over the operation in which the violative act occurred has always been present when individuals have been held vicariously liable.* It would seem, from the cases discussed thus far, that small businessmen run a particularly high risk since they generally are involved in plant operations, in addition to their overall responsibilities.

No cases have involved officers of large corporations who may be somewhat remote from the operations which resulted in violation, which brings us to the recent *Park* decision.

IV. The *Park* Decision

In November and December of 1971, an FDA inspection was made of the Baltimore warehouse of Acme Markets, Inc., of which John R. Park is president. The inspections uncovered evidence of rodent infestation of food, allegedly constituting a violation of Section 301(k), which prohibits the doing of any act with respect to a food held for sale after shipment in interstate commerce which

For footnotes to text, see pages 44—49.

results in such article being misbranded or adulterated. In late January of 1972, following the inspections, FDA wrote Park a letter advising him of conditions in the Baltimore warehouse. Park testified that he had read the letter, had been informed by his general counsel that the latter had discussed the matter with the Baltimore Divisional Vice President, and that that officer was investigating and would take corrective action. A subsequent inspection in March of 1972 revealed allegedly similar conditions to those found in the 1971 inspections. An informal Section 305 hearing was held in June of 1972 at FDA's Baltimore office. Park was invited but did not attend. He was represented by the Baltimore Divisional Vice President.

In March, 1973, a five-count information was filed against the corporation and Park as an individual defendant. While the corporation pleaded guilty, Park did not, and, at jury trial he was found guilty on all counts and fined a total of $250.

Park successfully appealed to the Fourth Circuit[71] on two grounds: (1) the trial court erred in its instructions to the jury, and (2) prejudicial evidence of a warning of alleged prior violations in a Philadelphia warehouse which were never prosecuted was improperly admitted. The Fourth Circuit reversed on both grounds. In a 2-1 decision, the court found that the jury charge did not correctly state the law of the case, reversed the conviction, and ordered a new trial.

The court concluded that *Dotterweich* cannot be read as predicating conviction "solely upon a showing that the defendant, Park, was the President of the offending corporation."[72] True, the court concluded, *Dotterweich* dispensed with "awareness of wrongdoing" as an element in conviction, but it did not dispense with the need to prove "wrongful action," which the Fourth Circuit defined as "acts of the accused which *cause* the adulteration of such food." (Emphasis in original.)[73] Those acts "may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' the contamination of the food."[74] The court further said that it must be proved that the defendant "was in some way personally responsible for the act constituting the crime," that he "participated directly or constructively therein" or that he was involved in a criminal conspiracy.[75] It is the defendant's relation to the criminal acts, not merely his relation to the corporation which the jury must consider, the court said.

For footnotes to text, see pages 44—49.

Thus the jury charge involved here was found improper. The Fourth Circuit described the jury instruction in this way:

"The court charged the jury that the sole question was 'whether the Defendant held a position of authority and responsibility in the business of Acme Markets,' that Park could be found guilty 'even if he did not consciously do wrong' and even though he had not 'personally participated in the situation' if it were proved beyond a reasonable doubt that Park 'had a responsible relation to the situation.' "[76]

The Fourth Circuit felt the instruction was improper, concluding as follows:

"In sum, the court told the jury that Park would be guilty if it were shown that he 'had a position of authority and responsibility in the situation out of which these charges arose.' This instruction, taken in combination with the other parts of the charge related above, might well have left the jury with the erroneous impression that Park could be found guilty in the absence of 'wrongful action' on his part."[77]

The Fourth Circuit clearly was impressed with the fact that Park is the chief executive officer of a multistate corporate giant, with only indirect supervisory responsibility over most of the company's employees.[78] He maintained his office in Philadelphia (not Baltimore where the alleged violations occurred), and "was theoretically in charge of approximately 36,000 employees in 874 retail outlets, 12 main warehouses and 4 special warehouses located on the east and west coasts of the United States."[79]

This factual setting was contrasted with *Dotterweich* where the defendant was responsible for 26 employees, all of whom worked on one floor of one building, where the defendant was responsible for general overseeing of the company operations and was the direct supervisor of all employees, and where he had direct personal supervisory responsibility over the physical acts which resulted in violations.[80]

The court stated "there is no allegation or proof that Park was responsible for the executive decisions which resulted in contamination of the food. The facts of *Dotterweich* established the personal responsibility which we find lacking in the case before us."[81] "To hold Park *criminally* liable," the court said, "for the wrongful actions of each and every one of these employees by merely showing his position with the corporation is manifestly unjust, unfair and beyond the realm of reasonableness."[82] (Emphasis in original.)

Circuit Judge Craven, in a dissenting opinion, argued that the instruction to the jury was proper, and that there was no attempt to equate presidency of the corporation with responsibility, stating that the trial judge

For footnotes to text, see pages 44—49.

"made it perfectly clear to the jury that 'the fact that the Defendant is present and is a chief executive officer of the Acme Markets does not require a finding of guilt. Though he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case. whether the defendant, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose.' "[83]

Judge Craven went on to note that the defendant had "conceded" that he had a responsibility to change the system of sanitation if it didn't work and that he had received a letter from the Food and Drug Administration in 1970 outlining insanitary conditions an inspection team had found in the Philadelphia warehouse. (The criminal information concerned conditions in 1972 in a Baltimore warehouse.) Expressing his sympathy for his fellow judges' "sense of justice" in wanting to invite into the statute "some small degree of *mens rea*," he also stated that he shared the government fear that the decision of the court would undermine the Congressional purpose of placing the burden "upon those who have at least the opportunity of informing themselves of the existence of" wrongful conditions, rather than "on the innocent public who are wholly helpless" to protect themselves from contaminated food.

Under the Supreme Court's interpretation of the Federal Food, Drug, and Cosmetic Act, the public is to be protected from adulterated and misbranded products, and "responsible" officials—within the meaning of *Dotterweich*—are held absolutely and vicariously criminally liable. The Supreme Court in 1943 refused to define the variety of conduct whereby persons may be held "responsible," leaving such matters to the "good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries."[84]

Since 1943, various courts have dealt with the issue and, thus far, individuals have been convicted only where close and immediate supervisory control over the plant or operation in which the acts occurred has been present. There are dicta that may go beyond that point, as noted before.[85] However, if the *Dotterweich* Doctrine is to be extended beyond the factual situations where conviction has resulted, surely Supreme Court guidance is indicated.

The criteria for holding persons "responsible" have been less than clear. The *Park* case at least demonstrates the need for Supreme Court guidance on the proper instructions for juries in this type of case. Jury instructions brought to light in this paper have been vague

For footnotes to text, see pages 44—49.

on the necessary relationship of the defendant to the business operations or the violative acts. Juries have been variously instructed:

"Are you satisfied from the evidence that shipment[s] were made under his supervision by him as 'General Manager'? It is not necessary for the Government to prove that he personally and physically made the shipment himself. It is sufficient if the evidence establishes to your satisfaction that it was made under authority conferred by him as general manager upon his subordinates. . . ."[86] (from *Dotterweich*)

And,

"if . . . any or all of the defendants shared responsibility in conducting the business and that the operation of that business resulted in unlawful distribution . . ., the defendants who shared such responsibility might be found guilty. . . . In determining whether the defendants did have a responsible share in the conduct of the business . . . [the jury] must take into consideration the work that each defendant did at the Kaadt Diabetic Clinic or Institute, the duties and responsibilities of each, and the extent to which each controlled or directed the conduct of the business."[87] (from *Kaadt*)

And, in the instant case, the jury was instructed that

"the fact that Park is present and is a chief executive officer of Acme Markets does not require a finding of guilt. Though he need not have personally participated in the situation, he must have had a responsible relationship to the issue. The issue is, in this case, whether the defendant, John R. Park, by virtue of his position in the company, had a position of authority and responsibility in the situation out of which these charges arose."[88] (from *Park*)

The *Park* case presents the issue foursquare—need the government prove, in order to convict, more than the fact that the defendant is the president of the offending corporation or otherwise in general charge of all its affairs? If so, does the government have to prove a relationship between the defendant and the specific violative acts? And, if not to the acts, then to the specific operation or plant in which the acts occurred? And what is the nature of the "relationship"? Need the defendant "cause" the adulteration in some way, as the Fourth Circuit suggests?

In short, how far does vicarious liability go? Who has, and under what conditions does he have, "a responsible share in the furtherance of the transaction which the statute outlaws"? When does he "aid and abet" in the commission of the violative acts? When does he share "responsibility in the business process resulting in unlawful distribution"?

Sufficient time has elapsed since 1943, sufficient cases have been before the courts, and there is sufficient confusion on the point to warrant Supreme Court guidance. Hopefully, such guidance will be forthcoming from the Court, which has granted *certiorari* in the *Park* case.

For footnotes to text, see pages 44—49.

V. Government Enforcement Policy and Procedures

In this section we will attempt to provide the reader with some insight into Government policy and procedures in enforcing the Act, with particular emphasis on decisions to prosecute individuals. Since the U. S. Attorneys' offices litigate food and drug matters on behalf of the government, an examination of policies and procedures necessarily must include not only those of the FDA, but also those of the Department of Justice and the U. S. Attorneys. We have sought to identify written policies of both agencies, and have supplemented those materials with conversations with government officials.[89]

The enforcement process usually begins with an inspection by an FDA field office investigator of the regulated facility, collection of samples, if any, and preparation of the investigator's report. This report is reviewed by a supervisory investigator in the field office and, if he concludes the situation warrants it, the report is forwarded through the Chief of the Investigations Branch to the Chief of the Compliance Branch. The Compliance Branch reviews the evidence and, if warranted, recommends legal or administrative action.

Whenever a District concludes that a warning letter is preferred in lieu of legal sanctions, a draft is prepared and submitted to the appropriate bureau for review. The purpose of the warning letter is to serve as a formal legal notice to firms and individuals of allegedly violative conditions and to provide the recipients an opportunity to act voluntarily. FDA hopes the letter will achieve prompt compliance with the Act in most instances. Follow-up inspections are often made to be sure the allegedly violative situation has been corrected in timely fashion. If not, further action, including the possibilities of seizure, injunction, and criminal prosecution, may be initiated.

In cases of imminent hazard to health, filthy conditions, or other extraordinarily serious matter, the warning letter may be bypassed and legal proceedings may be instituted instead.

In general, therefore, FDA policy provides for a "warning" to potential defendants and an opportunity to comply voluntarily. This has been described as "giving one bite at the apple."

While FDA policy provides for a "warning," it is silent as to the consequences of receiving such a warning. For example, a warning letter identifies specific violations alleged to have occurred in a

For footnotes to text, see pages 44—49.

specific facility on a specific date. Is that letter intended to put the addressee "on notice," for possible criminal prosecution purposes, that he may be prosecuted for *any* violation of the Act in *any* facility of his company from that point of time into the indefinite future—without further warning? This is simply not clear from existing policy.

In practice, of course, decisions to prosecute or take other action, are matters of judgment based on a particular set of facts. For example, if a subsequent inspection one year after an alleged violation was discovered showed the same violation in the same facility, the first warning may be deemed sufficient to recommend criminal prosecution. On the other hand, an inspection nine months after the first inspection which reveals a different violation in a different plant might warrant another letter rather than prosecution or other legal action.

While there are no published guidelines dealing with such matters, it should also be borne in mind that the regulatory letter procedure is not statutorily required before prosecution.

Decisions to prosecute always pass through several stages. After a Section 305 hearing, every recommendation for prosecution must be approved by the Regional and Deputy Regional Food and Drug Directors, the Compliance Division, the Director of the appropriate FDA Bureau in Rockville, Maryland headquarters, the Regulatory Management Staff of the Office of the Associate Commissioner for Compliance, and the Assistant General Counsel, Food and Drug Division, U. S. Department of Health, Education, and Welfare.

If a decision is made to prosecute, a letter is sent to the appropriate U. S. Attorney and the Department of Justice recommending prosecution. Either the Department of Justice or the U. S. Attorney may decline to prosecute.

While there are no written criteria defining "responsible persons," the documents reviewed are required to discuss:

> "a) the extent to which each individual defendant personally participated in the violations charged,
>
> b) the nature of the individual's position in the business,
>
> c) his duties and responsibilities in such position,
>
> d) facts, if any, showing that the individual knew or should have known the requirements of the law."[90]

Also, field investigators are instructed to look for evidence of responsibility for various major functions, such as sanitation and product quality control, who gives orders to clean the facility, who

For footnotes to text, see pages 44—49.

can stop and start operations and the like.[91] The investigators are told that "the identification of those responsible for violations is just as important as determining how violations occurred."[92]

In addition, before FDA recommends prosecution, it generally requires that (1) at least one responsible individual be identified and included in the prosecution, (2) there is substantial evidence to show that all individuals included in the prosecution had authority to correct the violative conditions, and (3) there is background which shows warning by inspection, letter, citation, prosecution, or other means of the firm and all individuals included in the prosecution, which warning issued prior to the last inspection on which the prosecution is based.[93]

The above summarizes the current FDA policy regarding criminal prosecution and enforcement. At the present time, FDA is working on a revised version of the Regulatory Procedures Manual. It should be noted that, in practice, FDA officials recognized the possibility of some unevenness of application, and it is for this reason that the Agency has provided for the multiple review of cases to assure as much fairness and uniformity of action as possible.

It is interesting to note, as we were informed, that the FDA General Counsel's Office considered about 100 requests for criminal prosecution in 1973 and forwarded about 90 of these to U. S. Attorneys. We were further informed that, generally, the reasons for not forwarding cases were lack of prior warning, failure of substantive proof, or failure to establish responsibility of individuals.

Justice Department officials informed us that they generally do not intervene to decline prosecutions recommended by FDA directly to U. S. Attorneys, and, to the best of the official's recollection, no intervention has occurred in the last year or so.[94]

U. S. Attorneys remain free to decline to prosecute despite FDA recommendations based upon local prosecutorial policy. In his extensive study on prosecutorial discretion in agency criminal referrals, Robert Rabin concludes that U. S. Attorneys decline to prosecute 10% of the cases referred by FDA. This is as low a refusal rate as he finds for any agency, and substantially lower than many.[95]

Rabin concludes:

"In sum, the Justice Department has no effective system of checking and reviewing the discretionary decisions of U. S. Attorneys regarding whether to prosecute."[96]

For footnotes to text, see pages 44—49.

In testimony in 1972 before a House Subcommittee, the FDA General Counsel testified that the Department of Justice or U. S. Attorneys declined or dismissed cases or individual defendants over the objection of FDA in about one-third of all FDA criminal cases over the previous five years.[97]

Rabin identifies some eight reasons which help explain refusals to prosecute. They are:

"1. case-load consideration;
2. magnitude of the violation;
3. court-perceived criminality of the offense;
4. special characteristics of the defendant;
5. existence of alternative sanctions;
6. adequacy of the case;
7. equality of treatment of regulated parties;
8. special-interest influences."[98]

The Food and Drug Administration, aware of how the U. S. Attorneys might react, may shape its enforcement policy accordingly. Rabin says:

"the enforcement policies of the SEC and FDA are shaped by the agencies' prediction of the prosecutor's response to the existence of alternative remedies. Both the SEC and FDA have powerful civil remedies that can be invoked in appropriate cases. Where a plant inspection by the FDA uncovers a series of violations, the agency is empowered to seize the merchandise involved. Or, the still softer remedy of warnings and publicity may be invoked. Only the case of the repeated offender will normally be referred to the U. S. Attorney. The SEC has a similar range of enforcement tools at hand, including publicity, injunction and a civil damage action, as well as criminal penalties. Only repeated offenses or egregious violations trigger resort to the criminal sanctions.

A consistent theme here is that repeated violators are prosecuted for acts which are handled in a noncriminal fashion where a first or infrequent offender is concerned."[99]

The above statement also helps explain the FDA's statements about its policy of giving individuals "one bite at the apple."

VI. Unreported Cases

In order to evaluate the application of the FDA policy, we had hoped to examine all criminal prosecutions brought over a number of years. However, we found that in the last five years there have been a total of 352 criminal prosecutions.[100] Such a large number made it impossible to examine each one. Therefore, we focused only

For footnotes to text, see pages 44—49.

on closed cases for the year 1973. There were, at the time of our review, 67 cases filed in 1973 that have since been closed. From these we randomly chose 20 to provide a sample. With the obvious caveat that the size of our sample was very limited, we are able to make a few generalizations.

The most noteworthy fact that arose was that all but one case examined were food sanitation cases involving adulteration under Sections 402(a)(3) or 402(a)(4), or both. This concentration of prosecutions involving food was also reflected by the FDA Annual Reports for the last five years which showed that food cases constituted 81.3% of all criminal prosecutions by FDA.[101]

FDA officials explained that the concentration in food sanitation, at least since 1972, is a result of a General Accounting Office audit report to Congress on April 18, 1972, which alleged that sanitary conditions in the food industry had deteriorated. As a result, FDA enforcement activity in this area was increased. Hoping to bring about self-correction on the part of industry, Mr. Sam Fine, FDA Associate Commissioner for Compliance, sent a letter to the trade associations of the involved industries on May 18, 1972, warning of increased enforcement in the area. Feeling this letter had received insufficient response, Mr. Fine, on August 30, 1972, sent a letter to the presidents of a number of food chains giving the same warning and stating:

"We regard you as the person who ultimately has the authority to order correction of such conditions, and thus who ultimately must bear the responsibility for any failure to correct them. Should it become necessary to bring criminal action to prevent a continuation of violative conditions, therefore, we wish you to understand that you and other high corporate officials in your organization who are specifically responsible for sanitation practices will be held accountable."[102]

This helps explain the heavy concentration of prosecutions in the food area and sheds some light on who FDA considers a responsible individual. It may also help to explain the decision to file the *Park* case.

In other respects the review of the twenty cases revealed no important deviations from the enforcement policy of the Agency. Almost invariably, the president of the corporation or owner of the business was charged. In most instances, he was the individual involved in the day-to-day operation and management of the business and the one who had the authority to institute necessary changes. If the president of the corporation was not actively involved in its affairs, another more directly responsible corporate officer would be

For footnotes to text, see pages 44—49.

charged instead. Most of the firms had a history of prior sanitation problems. In every case some form of warning and follow-up inspection was provided. Section 305 hearings were held as a matter of course. We found no cases where a term of imprisonment had been imposed. Guilty pleas were the rule. Indeed, given the warnings and subsequent acts of omission in a number of instances, it could be said there were both awareness of wrongdoing and wrongful action on the part of individuals prosecuted in these cases. Of course, whether such knowledge and wrongful action could meet the standards of legal proof of intent imposed in most criminal prosecutions remains another matter. At any rate, however, those elements were not wholly lacking.

Thus, routine application of the *Dotterweich* Doctrine by the government—based on our limited sample and the limited information with regard to unreported cases which we were able to obtain—does not raise serious questions about administrative abuse.

VII. Policy Considerations

Having concluded our discussion of the legal limits to which the *Dotterweich* Doctrine has in fact been applied, and having touched on the practical application of the doctrine by the relevant governmental agencies, we will now turn our attention to a review of the policy considerations and implications of the concepts of absolute and vicarious criminal liability.

In order to provide a more complete framework for consideration of the policy issues, it will be helpful to know something of how the doctrine relates to general criminal jurisprudence, as well as the enforcement mechanisms provided in other federal health and safety related statutes.

A. *Dotterweich* and General Criminal Jurisprudence

Our purpose here is not to engage in a lengthy dissertation on criminal law and the many complexities involved in determining the requisite mental element for crimes. Rather, we hope briefly to outline—at the risk of over-simplification—some basic concepts of criminal law and to place the *Dotterweich* Doctrine into perspective in our system of criminal jurisprudence.

Generally, of course, some element of intent is necessary in order to sustain criminal conviction.[103] In some situations, only a general

For footnotes to text, see pages 44—49.

intent is required. General intent has been defined as showing that a person has knowingly committed an act which the law makes a crime, from which the required intent may be inferred.[104] In other situations, a specific intent is necessary. Specific intent requires proof that a person knowingly committed an act which the law forbids, intending with bad purpose either to disobey or disregard the law.[105] Certain defenses, such as mistake of fact, may be available, and the presumption of intent inferred from commission of an act also may be rebutted.[106] Generally, persons are not held criminally responsible for acts which they did not personally commit or in which they did not take part.[107]

In the case of statutory crimes, as distinguished from those found in common law, one looks to the statute to determine the necessary mental element required for conviction. The threshold question is the intent of Congress. Statutes frequently are silent as to whether intent is required and even where words such as "knowingly," "willfully," "feloniously," and "negligently" are used in the statute, the required mental element still may be unclear. As Francis Bowes Sayre says in his excellent article on *Mens Rea:*

"Even though the statutory requirements for a specific intent are laid down for two crimes in the same words, not infrequently the meanings to be attached to the same word formulae differ vastly."[108]

Thus, in order more fully to understand the meaning and intent of Congress, regardless of which, if any, statutory words are employed, one must look not only to the words of the section of the statute at issue, but also to its general framework and purpose, and to its legislative history.

Public welfare offenses have been treated in a special way in criminal law.[109] In his article on *Public Welfare Offenses,* Sayre broadly categorizes public welfare offenses as including sales of intoxicating liquors, sales of impure or adulterated food or drugs, sales of misbranded articles, violations of antinarcotic acts, criminal nuisances, violations of traffic and motor vehicle laws, and violations of laws involving health, safety, or community well-being.[110] Lack of awareness of wrongdoing in committing an illegal act has been held to be irrelevant for conviction of public welfare offenses since the emphasis of the statute is to achieve a social goal rather than to punish a crime. The simple doing of the act is sufficient and absolute.[111]

A major case in point is *United States v. Balint,*[112] where defendants, charged with selling narcotics in violation of law, demurred to the

For footnotes to text, see pages 44—49.

indictment on the ground that it failed to charge that defendants made the prohibited sale knowing it to be illegal. The relevant statute was silent on requiring knowledge as an element of the crime. Chief Justice Taft, speaking for the Supreme Court, said:

"In the prohibition or punishment of particular acts, the state may, in the maintenance of a public policy, provide 'that he who shall do them, shall do them at his peril, and will not be heard to plead in defense good faith or ignorance.' "[113]

In describing the "particular acts," the Chief Justice said:

"Many instances of this are to be found in regulatory measures in the exercise of what is called the police power, where the emphasis of the statute is evidently upon achievement of some social betterment rather than the punishment of the crimes. . . ."[114]

Amplifying the rationale of not requiring intent, the Court used language reminiscent of *Dotterweich,* saying:

"Its [the statute's] manifest purpose is to require every person dealing in drugs to ascertain at his peril whether that which he sells comes within the inhibition of the statute, and, if he sells the inhibited drug in ignorance of its character, to penalize him. Congress weighed the possible injustice of subjecting an innocent seller to a penalty against the evil of exposing innocent purchasers to danger from the drug, and concluded that the latter was the result preferably to be avoided."[115]

Thus, the *Dotterweich* Doctrine of imposing absolute criminal liability upon persons who had no awareness of wrongdoing in committing a violation of a public welfare statute seems to fall into an accepted area of criminal jurisprudence. Sayre sees justification for absolute liability only where the offense involves:

"a social injury so direct and widespread and a penalty so light that in exceptional cases courts could safely override the interest of the individual defendants and punish without proof of any guilty intent."[116]

He warns against dangerous extensions of the doctrine. To the extent that the absolute liability concept of *Dotterweich* has been applied to violations that are merely economic and involve no threat to health, and where prison sentences have resulted, the doctrine appears to be on the fringes of our criminal jurisprudence.[117]

Implicit in this discussion has been the concept that the defendant personally committed the act which was a violation of law. The other portion of the *Dotterweich* Doctrine—that of vicarious liability—has also been treated in the literature. Sayre, in another old, but excellent, treatise entitled *Criminal Responsibility for Acts of Another* states:

"Vicarious liability is a conception repugnant to every instinct of the criminal jurist. It is not surprising, therefore, that courts today as a general rule . . . make criminal liability exclusively dependent upon causation. Causation may

For footnotes to text, see pages 44—49.

be proved either (1) by authorization, procurement, incitation or moral encouragement, or (2) by knowledge plus acquiescence."[118]

Sayre notes, in a summary conclusion to his article, that in certain "exceptional groups of cases," the courts have departed from requiring causation as defined above as the basis of criminal liability. He defines these "exceptional groups of cases," where individuals are held criminally responsible for acts of another, as follows:

> "(a) In public nuisance cases, the owner of the premises has been held liable for unauthorized nuisances wrought by servants.
>
> (b) In libel cases, the courts have allowed the authorization of the master to be proved . . . by a rebuttable presumption of law.
>
> (c) In statutory crimes, proof of authorization or consent may be dispensed with under the terms of the statute or under legal interpretations of its terms.
>
> (d) In the liquor cases, there is hopeless conflict of decisions."[119]

Sayre states his policy conclusion on the issue of criminal responsibility for acts of another in these terms:

> "In the case of felonies and all serious crimes, criminal law should reject the doctrine of *respondeat superior* and rest criminal liability exclusively upon causation.
>
> In the case of petty misdemeanors involving no moral delinquency where the penalty is no more than a slight fine and public policy so requires, proof of actual authorization or knowledge should not be required."[120]

Thus, the concepts of absolute and vicarious criminal liability as set forth in *Dotterweich* appear to be "relatively unique," but not without precedent. Perhaps the most unique aspects lie in the application of the doctrine to economic violations, in applying prison sentences, and cases charging felony violations for second convictions.

B. Enforcement Mechanisms in Other Statutes

In this section we will analyze the results of a survey of twenty-seven federal statutes which relate to health or safety in order to determine the enforcement mechanisms employed by Congress in those statutes. This will help shed light on the degree of "uniqueness" of the enforcement mechanisms of the Food, Drug, and Cosmetic Act as interpreted and will help identify various enforcement alternatives which have been enacted by Congress.

A summary of the survey is attached as Appendix I to this paper and the results of the survey are reported in more depth in Appendix II. We have sought briefly to define the basic objective of each stat-

For footnotes to text, see pages 44—49.

ute insofar as relevant, the nature of major violations of it, and the enforcement mechanism provided, with particular emphasis on criminal provisions and whether or not "knowledge" is an essential element for criminal conviction. We have also noted the dates of enactment and major amendments to the statutes since that may have some bearing on trends in Congress in providing enforcement mechanisms. We did not delve into legislative history or case law of the various statutes. While the survey does not purport to be exhaustive of all federal health or safety-related statutes, efforts were made to report major legislation of this type.

Before proceeding with the analysis, it will be helpful briefly to review the nature of violations of the Federal Food, Drug, and Cosmetic Act, and the enforcement mechanism of that Act.

Section 301[121] lists the acts prohibited by the statute. Several of the prohibited acts refer to the adulteration or misbranding of foods, drugs, devices, or cosmetics. The terms adulteration and misbranding, with respect to each of these articles, are defined in the statute. In total there are over sixty subsections listing one or more acts which ultimately are violative of Section 301.[122]

Acts constituting violation of Section 301 run the gamut. Some involve safety-related acts; others relate solely to economic matters, and violative acts vary in terms of the risk to public health and safety. Prohibited acts include:

— failure to maintain or permit access to records required by law;
— refusal to permit inspections authorized by law;
— giving false guarantees;
— counterfeiting;
— divulging information protected under trade secret laws;
— failure to register a drug manufacturing establishment;
— failure to provide reports as required by law;
— introduction into interstate commerce or receipt in interstate commerce of a food or cosmetic which contains poisonous substances which may render it injurious to health;
— introduction into interstate commerce or receipt in interstate commerce of a food, drug, device or cosmetic consisting in whole or in part of any filthy, putrid or decomposed substance, or processed under insanitary conditions;
— introduction into interstate commerce or receipt in interstate commerce of a food, drug, device, or cosmetic whose

For footnotes to text, see pages 44—49.

labeling is false or misleading, whose container is misleading, whose label does not contain the name and place of business of the manufacturer, packer or distributor, or whose quantity is not accurately stated on the label.

There are several enforcement mechanisms set forth in the Act in order to secure compliance. In addition to possible criminal prosecution of corporations and individuals, injunctive relief may be sought in court to restrain violations.[123] Seizure and condemnation actions (including in some instances multiple seizure actions) also may be brought in court against adulterated or misbranded articles.[124] Also, product recalls have been employed as an enforcement mechanism, although there is no express statutory authorization for their use.[125] There are no civil penalties under the Act.

The criminal penalty provisions of the Act are set forth in Section 303(a) which provides that "any person who violates a provision of Section 301 [which lists all of the prohibited acts of the statute] shall be imprisoned for not more than one year or fined not more than $1,000, or both."[126] "Person" is defined in the Act to include individuals, partnerships, corporations, and associations.[127] Offenders convicted of a second offense and those committing a violation with intent to defraud or mislead are subject to felony conviction with a maximum three-year prison term, and a $10,000 fine, or both.[128]

The Act also provides several limited express defenses which may be raised to avoid the penalties provided in Section 303(a).[129] And Section 305 provides that "before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding."[130] The Act also provides that the Secretary need not report for prosecution minor violations of the Act whenever he believes the public interest will be adequately served by a suitable written notice or warning.[131]

One could engender a great deal of discussion in comparing the enforcement mechanisms of the statutes surveyed with that of the Food, Drug, and Cosmetic Act. Such questions as the similarity—or lack thereof—in the purposes of the statutes can be raised as well as the degree of focus by the Congress on the enforcement mechanism.

For footnotes to text, see pages 44—49.

We will not attempt to be exhaustive in the ensuing discussion, but a few observations will be made.

Perhaps the most obvious conclusion is that the enforcement mechanisms of the statutes vary widely, both in terms of enforcement tools and in severity of sanctions. Some statutes authorize seizure, some do not; some authorize injunction, some do not; some authorize detention, some do not; some employ criminal sanctions, some do not; some employ civil penalties, some do not; and some employ both civil and criminal penalties while others do not.

The maximum fines applicable in civil penalty cases range from a low of $1,000 to a high of $25,000 for certain violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970. In some statutes, civil penalty provisions are written so as to make the fine apply to each product involved in a violation or for each day of violation, resulting in a civil penalty exposure of $300,000—$500,000 for a related series of violations. In most cases, the statutes do not expressly state whether an individual can be personally assessed for acts he or another committed, and we have not examined case law or legislative history on this point.

The maximum prison terms applicable in criminal cases vary from 30 days to over fifteen years, with one year as the most typical. The maximum criminal fines vary from $500 to $50,000.

The variety found in enforcement mechanisms and severity of sanction is not surprising. While we have not attempted to relate "punishment to the crime," presumably Congress attempted to do so in its deliberations on the various statutes. The variety is perhaps better explained by the fact that the various statutes were considered by different legislators, on different Congressional committees, at different times. There simply is no common thread—or at least we have not been able to discover one.

With respect to the necessity of the element of "knowledge" required to result in criminal conviction, we were hampered by the lack of a study of the case law or legislative history of the statutes reviewed. However, of the twenty-seven statutes reviewed (other than the Federal Food, Drug, and Cosmetic Act), twenty-three authorize criminal sanctions[132] and, of these twenty-three, thirteen expressly require "knowledge" or a similar element for criminal conviction by their statutory language.[133] Ten statutes are silent on the point[134] and, of these, we know of one which has been interpreted in court to

For footnotes to text, see pages 44—49.

require knowledge as a necessary element for criminal conviction,[135] and of three which have been interpreted in court not to require knowledge.[136] Two statutes employ the enforcement mechanism of the Food, Drug, and Cosmetic Act with respect to articles under the statute which are regulated under the food and drug law.[137] The fact that a statute is silent on the issue of "knowledge," of course, does not necessarily mean that "knowledge" is or is not required.

It is also noteworthy that, of the eleven statutes related to food,[138] five required knowledge as a statutory element for conviction,[139] six are "silent;"[140] and of the six "silent" statutes, one has been interpreted in court to require knowledge as a necessary element for criminal conviction,[141] and two have been interpreted not to require knowledge.[142]

With respect to the issue of whether a defendant can be held criminally liable for the act of another, six of the twenty-three statutes providing criminal sanctions which were reviewed (other than the Federal Food, Drug, and Cosmetic Act) expressly provide some form of vicarious liability,[143] and sixteen are "silent" on the point.[144] Of the eleven food-related statutes, three provide a form of vicarious liability,[145] and eight are "silent."[146] The Federal Coal Mine Health and Safety Act contains language which seems to preclude vicarious liability.[147] Again, the mere fact that a statute is "silent" does not necessarily mean that vicarious liability is not possible.

The more recently enacted statutes seem to present a trend toward increasing administrative flexibility in the variety of enforcement tools available,[148] toward an increase in the maximum monetary penalties, [149] and toward requiring knowledge as an element in individual criminal liability.[150] Indeed, several recent statutes contain no criminal penalties,[151] and several recent statutes require "knowledge" for criminal, but not civil, penalties.[152] The Drug Abuse Prevention and Control Act of 1970 reflects unusual sophistication in the approach to penalties and the Consumer Product Safety Act is unique in that it provides great flexibility in terms of enforcement tools, including high civil penalties; but, for criminal conviction, knowledge, willfulness and violation of a prior order are necessary.

It is also noteworthy that the severity of enforcement frequently varies considerably for offenses which seem to be similar. For example, knowledge is required by statute for criminal conviction in the case of several food-related laws, but not for other food-related laws.

For footnotes to text, see pages 44—49.

Also, in the case of violations of the Poison Prevention Packaging Act and the Fair Packaging and Labeling Act, penalties vary according to the product involved because each of those laws employs the enforcement mechanism of the different substantive statutes regulating products to which those acts apply.

While the limits of our survey require extreme caution in making generalizations, it does appear that the Food, Drug, and Cosmetic Act is at least "relatively unique" in federal law in subjecting defendants to absolute and vicarious criminal responsibility for violations.

C. Absolute and Vicarious Criminal Liability—Pros and Cons

The intent of Congress in enacting the Federal Food, Drug, and Cosmetic Act has been interpreted by the Supreme Court as holding individuals absolutely and vicariously criminally liable for adulteration and misbranding violations. There are many nuances and distinctions which can be drawn in interpreting the *Dotterweich* opinion and subsequent cases. Our purpose in this section of the paper is simply to *identify* the major pros and cons of the *basic concepts* of strict and vicarious liability in order to help focus the attention of the reader on the issue of whether or not those concepts represent sound overall public policy.[153] We will not attempt to engage in a discussion of the innumerable subtleties related to the distinctions and nuances in the cases, nor will we engage in a discussion of the many alternatives to the present concept, as interpreted by the Court, which are available.

The central argument in favor of absolute and vicarious criminal liability is based on the theory that the doctrine *best protects the public,* by providing the *best possible deterrent to violations* of the Act by *motivating businessmen to seek to attain the highest possible standard of care* by taking affirmative action and by instituting necessary safe and sound practices to assure that violations do not occur, lest they be branded criminals and risk imprisonment. The rationale is that the businessman, who places before the consumer a product which can harm him, is in a better position to assure product integrity than is the consumer, who is helpless. The statute is intended to protect the public rather than punish the offender; therefore, his knowledge of a violation is irrelevant. The consumer is equally harmed whether or not the defendant knew of the violative acts.

For footnotes to text, see pages 44—49.

Additional major arguments in favor of the concepts are that they help to make the law largely self-executing, thus enabling a small enforcement staff more effectively to oversee billions of dollars worth of commodities; that they discourage legal "brinksmanship" (encourage business always to resolve doubts in favor of protecting the public); that other methods of enforcement, such as civil penalties, may be viewed as a cost of doing business and will not be as effective in protecting the public; that the doctrine has not been abused by the government, and that the courts will prevent its abuse, if necessary. Also, it is argued, proof of knowledge or willfulness often would be difficult since few would intentionally place harmful products on the market and knowledge and willfulness are irrelevant to the public purpose of the doctrine. Requiring such proof, it is argued, would defeat the public protection purpose of the Act.

The central arguments against absolute and vicarious criminal liability are that it is *unjust* and that *alternative enforcement mechanisms* are in the Act or could be placed in the Act by Congressional amendment which would be *at least as effective in protecting the public*. It is argued that it is manifestly unjust to hold a man *criminally* responsible for acts which he did not commit, know of, and may not have been able to prevent even with a very high standard of care. Other statutes of great importance to the health and safety of the public are enforced without resort to absolute and vicarious liability, and there is no evidence that these statutes are observed by businessmen any less than the Federal Food, Drug, and Cosmetic Act. Indeed, some may argue that a variety of enforcement tools may lead to better enforcement than absolute and vicarious criminal liability because courts and juries often may not be prone to convict criminally—or U. S. Attorneys to prosecute—in the absence of some element of wrongdoing, and may therefore be inclined to penalize lightly even on conviction.

Additional major arguments against the doctrine are that it is unjust to subject individuals to the possibility of prosecution where, as is often the case, the requirements of the Act are not absolutely clear, where violations are not related to health or safety, where a felony is charged for a second conviction, or where prison terms are imposed. It is further argued that, if an individual exercises a reasonable degree of care under the circumstances, and did not know of a violation, the rationale of deterrence is inapplicable. Thus, the public really is not protected in such an instance; rather, an innocent person may be branded a criminal. Also, it is argued, the threat of criminal prosecution may

For footnotes to text, see pages 44—49.

be used unfairly as a lever by the government to demand, beyond the requirements of the law, that a company take or not take action in other matters. The potential for abuse is sufficient to justify elimination of the doctrine. Finally, it is argued that the integrity of criminal justice demands extreme care in defining criminal conduct, lest innocent individuals be branded criminals, thereby weakening the stigma attached to criminal conviction, and thereby impairing its deterrent effect.

Professor Sayre poses the basic policy issue well when he says:

"All criminal law is a compromise between two fundamentally conflicting interests. In the first place, there is the social interest in the general well-being and security. . . . In the second place, there is the individual interest of the particular defendant against the restraint of his liberty for offenses for which he was not morally blameworthy."[154]

It would seem that these arguments with respect to absolute and vicarious criminal liability, coupled with the effectiveness of alternative enforcement mechanisms, constitute the essential areas of debate; and that the continuance, abandonment, or modification of the *Dotterweich* Doctrine will depend on how these issues are resolved in the future.

VIII. Summary and Conclusion

As applied by the courts since 1943, the *Dotterweich* Doctrine has come to mean that "responsible" individuals can be criminally convicted for violation of the Act. The scope of the doctrine is quite broad in the sense of the products and violations to which it applies, the potential defendants, and the nature of the punishment imposed.[155]

While the theory of the decision is quite broad in terms of who can be held a "responsible" party, the litigated and reported cases involve conviction of individuals in situations only where close and immediate supervisory control by the defendant over the operation in which the violative act occurred has been present,[156] although jury instructions have been quite vague.[157]

The *Park* case, on the other hand, convicted an individual defendant who apparently did not have such a close connection with the operation, although perhaps the defendant had reason to know of conditions in the operation where the allegedly violative acts occurred.[158]

Assuming acceptance of the *Dotterweich* Doctrine, one can still legitimately ask the question, is it fair to hold the president of a large corporation, or any defendant, criminally responsible for acts performed only under his very general supervision? The "authority and

For footnotes to text, see pages 44—49.

responsibility," as a practical matter, of someone on the scene differs substantially from the theoretical "authority and responsibility" of someone not on the scene who carries the title of president and who has the "authority and responsibility" for a wide range of activities. In the cases examined in this paper, defendants have not been convicted where they were not in a position of fairly close proximity to the specific situation resulting in violative acts. Though many of the defendants may not have known of the acts as they occurred, they were on the scene or very close to it. This is not to say that a president of a large concern might not be similarly situated. However, to the extent that such an individual could not reasonably have known of the violation or conditions which reasonably could lead to violation, perhaps it is not only unfair, but ineffective, to hold him criminally liable.

However, if such a distinction is to be drawn between individuals such as Dotterweich who are close to the situation and those like Park who may not be, should the legal theory of distinction be premised on a finding of "wrongful action"? *Dotterweich* is ambiguous as to whether or not "wrongful action" (as defined by the Fourth Circuit to mean "acts of the accused which cause the adulteration of . . . [the] food") is required for conviction.

Is not a main difference between Dotterweich and Park that the former had a direct supervisory role, whereas the latter had an indirect role (unless the facts show a more intimate connection with the operation where the acts occurred or other reason requiring a prudent man to take whatever action would be reasonable under the circumstances)?

Whether the "responsibility and authority" is direct or indirect would appear to be a question of remoteness. But how can one say that either "caused" the violative acts? Perhaps a more proper standard is that of "reasonableness"—*did the defendant know—or should he reasonably have known—of conditions in the plant or operation which reasonably could result in violative acts*—regardless of his title and general position and authority in the company?

Alternatively, one could devise a two-pronged jury instruction which even more clearly than the above would hold liable anyone who was found to be in close proximity to the operation or plant where the violation occurred, as well as permit a jury to hold liable anyone who, while not personally close to the operation or plant,

For footnotes to text, see pages 44—49.

should reasonably have known of the conditions in the plant or operation which could reasonably result in violative acts. For example, the question could be posed to the jury: *Was the defendant reasonably close to the plant or operation where the violative act occurred or should he otherwise reasonably have known of the conditions which reasonably could result in violative acts?*

The main difference between this latter standard and that first suggested is that the former might not allow the attaching of liability to defendants similarly situated to the defendants in the litigated cases we have examined—all of whom were, in fact, in close proximity to the plant or operation. The latter standard would, even more clearly than the one first suggested, preserve the elements of vicarious and absolute liability, and, at the same time, inject a rule of reason with respect to those who are in fact not in close proximity to the plant or operation, and who could not reasonably have known of conditions in the plant or operation which reasonably could result in violative acts. One could argue that this latter instruction, more clearly than the first, would reduce the burden on the government to prove reasonableness in every case and would reduce the possible burden on the government resulting from a situation where defendants, by delegating their authority, would unjustifiably or purposefully attempt to insulate themselves from liability. The theory would be that they reasonably could not have known of problems in the area that their delegate was to manage. Perhaps it could be argued that the affirmative duty to find out what is going on, even if one did not know of the conditions, is stronger where the officer is in close proximity to a single operation or plant than where the officer is in charge of a multifaceted operation.

Are not both such instructions consistent with the rationale of the *Dotterweich* case to protect the public and place the burden of compliance on those who introduce goods into commerce? For how could one who could not reasonably know of conditions which could reasonably result in violative acts do anything to protect the public, at least where he was not in close proximity to the hazard? In raising these questions, we are mindful of the argument that absolute and vicarious liability raises the degree of care and attention to such matters as sanitation. But we are also mindful of the fact that we are speaking here of underlying *criminal* liability. The public is not without protection since, under the standards suggested, a president or other senior

For footnotes to text, see pages 44—49.

officer could be convicted, and, in any event, under either standard, there will be one or more "responsible" parties. Further, we are mindful of the fact that theoretically *Dotterweich* can be used to prosecute a wide range of offenses and of the fact that large businesses have diverse and numerous activities, products, and operations. Is it *possible* to be informed on all possible violative conditions in such circumstances?

While *Dotterweich* is somewhat on the fringe of criminal jurisprudence in subjecting defendants to possible criminal conviction when they not only did not know an act was a violation and had no criminal intent, but also when they did not commit, authorize or know of the act in question, would it not go beyond the pale of justice to apply the doctrine (at least where the defendant is not in close proximity to the plant or operation) to a defendant who could not reasonably have known of conditions which reasonably could result in violative acts?

Hopefully, the Supreme Court will give further guidance in the *Park* case.

From our limited study of government policies and procedures in applying the *Dotterweich* Doctrine, it appears that FDA generally gives warnings before prosecuting individuals and that there are fairly extensive procedures before a decision to prosecute is reached, and our limited survey of unreported cases does not raise serious questions of abuse of the doctrine.[159]

While the concepts of absolute and vicarious criminal liability appear to be "relatively unique" in criminal jurisprudence, they are not without precedent.[160] And our study of enforcement mechanisms in other statutes shows a wide range of alternatives and points up the need for Congress to be more precise in expressing its intent in matters of absolute and vicarious liability.[161]

The ultimate resolution of policy issues concerning absolute and vicarious criminal liability involves a balance between the rights of individuals and the need to protect the public. There are few issues in law and public policy which are as important as resolving this balance and we hope that this paper has helped to put the issues in context insofar as the Federal Food, Drug, and Cosmetic Act is concerned.

For footnotes to text, see pages 44—49.

FOOTNOTES

[1] Federal Food, Drug, and Cosmetic Act § 1 [hereinafter cited as the Act], 21 U. S. C. § 301 (1970).

[2] 320 U. S. 277 (1943).

[3] Section 303(a) provides: "Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both." (21 U. S. C. § 333(a) (1970).) Section 301 prohibits, *inter alia*, the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded drug. (See the Act, § 301(a), 21 U. S. C. § 331(a) (1970).) Adulterated and misbranded drugs are defined in the Act in §§ 501 and 502, respectively, 21 U. S. C. §§ 351, 352 (1970).

[4] *United States v. Buffalo Pharmacal Co.*, 131 F. 2d 500, 501 (2d Cir. 1942).

[5] *Id.* at 501-502.

[6] *Id.*

[7] U. S. Supreme Court Transcript of Records, Vol. 11, at 16, *United States v. Dotterweich*, 320 U. S. 277 (1943).

[8] *Id.* at 164.

[9] *United States v. Buffalo Pharmacal Co., supra* note 4 at 501.

[10] 131 F. 2d 500 (2d Cir. 1942).

[11] The Second Circuit interpreted the word "person" in Section 303(a) to mean the principal, whether a corporation or individual proprietor, who caused the introduction or delivery for introduction of a violative drug into interstate commerce. The court found that the general manager could not be found guilty unless it could be shown that the corporation was his alter ego. The rationale was that only a person who would receive a "guaranty" under Section 303(c), thus providing a statutory defense, could be a "person" who could be held liable under Section 303(a).

[12] *United States v. Dotterweich*, 320 U. S. 277 (1943).

[13] The Court found that corporate acts are accomplished and furthered by persons standing in various relations to the corporation and that the Act is concerned with distribution of misbranded or adulterated drugs, not with proprietary relations to them. See *United States v. Dotterweich, supra* note 12 at 281-84.

[14] *Id.* at 281, quoting *United States v. Johnson*, 221 U. S. 488, 497 (1911).

[15] *Id.* at 284.

[16] *Id.* at 284-85.

[17] *Id.* at 285.

[18] *Id.* at 286.

[19] 499 F. 2d 839 (4th Cir. 1974), *petition for cert. granted*, 43 U. S. L. Week 3273 (U. S. Nov. 12, 1974) (No. 74-215).

[19a] Also, while we do not here deal with the legislative history of the Act relevant to the doctrine, it is certainly noteworthy that, in 1947 and 1948 several witnesses before a Senate committee urged that the Act be amended to require intent for criminal conviction. See "Amendments to Food and Drug Act," *Hearings on S. 1190 and H. R. 4071 Before a Subcommittee on Interstate and Foreign Commerce*, United States Senate, 80th Cong., 2d Sess., at pages 19-25 (1948). The Senate-passed bill would permit criminal conviction only for violations committed "willfully or as a result of gross negligence." (93 *Cong. Rec.* 6941-6942 (June 1, 1948) (daily ed.).) The above language was stricken in conference. (93 *Cong. Rec.* 8996-8997 (June 18, 1948) (daily ed.).)

[20] 138 F. 2d 437 (3d Cir. 1943).

[21] *Id.* at 439.

[22] *Accord, United States v. Hohensee,* 243 F. 2d 367 (3d Cir. 1957), *cert. denied,* 353 U. S. 976 (1957), where an individual defendant unsuccessfully argued that intent should be an element where felony penalties would apply. Felony penalties apply to violations of the Act where a person is convicted of a second violation or where there has been an intent to defraud or mislead. See the Act, § 303(b), 21 U. S. C. 333 (b) (1970). See also *United States v. Sullivan,* 332 U. S. 689 (1948).

[23] *United States v. Dotterweich, supra* note 12. In the *Dotterweich* case, the defendant, while not accorded a Section 305 hearing in his individual capacity, did appear at such a hearing held for the corporation.

[24] 163 F. 2d 1008 (7th Cir. 1947), *cert. denied,* 332 U. S. 851 (1948).

[25] *Id.* at 1010.

[26] 335 U. S. 345 (1948).

[27] See *United States v. Kordel,* 164 F. 2d 913, 916 (7th Cir. 1947).

[28] See also *V. E. Irons, Inc. v. United States,* 244 F. 2d 34, 43 (1st Cir. 1957), *cert. denied,* 354 U. S. 923 (1957). Mistake of law, of course, is not generally a defense.

[29] See *Kordel v. United States, supra* note 26 at 352-54.

[30] *United States v. Kordel, supra* note 27 at 917. See also *Drown v. United States,* 198 F. 2d 999, 1006 (9th Cir. 1952), *cert. denied,* 344 U. S. 920 (1953).

[31] 171 F. 2d 600 (7th Cir. 1948).

[32] *Id.* at 604.

[33] Brief for Appellee at 38-39, *United States v. Kaadt,* 171 F. 2d 600 (7th Cir. 1948).

[34] 209 F. 2d 166 (9th Cir. 1953).

[35] Brief for Appellants at 50-51, *Golden Grain Macaroni Co. v. United States,* 209 F. 2d 166 (9th Cir. 1953).

[36] *Golden Grain Macaroni Co. v. United States, supra* note 34 at 168.

[37] 215 F. 2d 95 (2d Cir. 1954).

[38] *Id.* at 99.

[39] Brief for Appellee at 2, *United States v. H. Wool & Sons, Inc.,* 215 F. 2d 95 (2d Cir. 1954).

[40] *Id.* at 1.

[41] 125 F. Supp. 617 (D. Delaware 1954).

[42] FDA Notice at Judgment 23242, March 1957.

[43] *United States v. Diamond State Poultry Co., supra* note 41 at 619.

[44] *Id.* at 620.

[45] 376 U. S. 86 (1964).

[46] *Id.* at 91.

[47] *Id.*

[48] 491 F. 2d 335 (6th Cir. 1974).

[49] *Id.* at 337.

[50] CCH F. D. COSM. L. REP. (Developments 1973-1974) para. 41,111 at page 40,543 (Docket No. 73-1744, 7th Cir., March 14, 1974), *petition for cert. filed,* 43 U. S. L. Week 3258 (U. S. Oct. 29, 1974) (No. 74-142).

[51] *Id.* at page 40,547.

[52] *Id.*

[53] *Id.* at page 40,548.

[54] See *United States v. Siler Drug Store Co.*, 376 F. 2d 89 (6th Cir. 1967); *United States v. Kaadt, supra* note 31. See also *United States v. Sullivan*, 332 U. S. 689 (1948); *United States v. Moore*, discussed in Nelson, *Druggist Beware!*, 9 FOOD DRUG COSM. L. J. 163 (1954).

[55] See *United States v. Cassaro, Inc.*, 443 F. 2d 153 (1st Cir. 1971); *United States v. H. Wool & Sons, Inc., supra* note 37; *Golden Grain Macaroni Co. v. United States, supra* note 34; *United States v. Diamond State Poultry Co., supra* note 41.

[56] See *United States v. Parfait Powder Puff Co., supra* note 24.

[57] See *United States v. H. Wool & Sons, Inc., supra* note 37. See also *United States v. Omar*, 91 F. Supp. 121 (D. Nebraska 1950).

[58] See *United States v. H. Wool & Sons, Inc., supra* note 37.

[59] See *United States v. Siler Drug Store Co., supra* note 54. See also *United States v. Sullivan, supra* note 54; *United States v. Moore, supra* note 54.

[60] See *United States v. H. B. Gregory Co., supra* note 50.

[61] See *United States v. Kocmond*, 200 F. 2d 370 (7th Cir. 1952).

[62] See *United States v. Siler Drug Store Co., supra* note 54; *United States v. H. Wool & Sons, Inc., supra* note 37; *United States v. Kaadt, supra* note 31.

[63] See *United States v. Diamond State Poultry Co., supra* note 41.

[64] See *United States v. Dotterweich, supra* note 2; *Golden Grain Macaroni Co. v. United States, supra* note 34.

[65] See *United States v. H. Wool & Sons, Inc., supra* note 37.

[66] See *United States v. Hohensee, supra* note 22.

[67] See *United States v. Dotterweich, supra* note 2.

[68] *United States v. Dotterweich, supra* note 2 at 286 (Justice Murphy, dissenting).

[69] *United States v. Diamond State Poultry Co., supra* note 41 at 620.

[70] *United States v. H. B. Gregory Co., supra* note 50 at page 40,547.

[71] *United States v. Park*, 499 F. 2d 839 (4th Cir. 1974), *petition for cert. granted*, 43 U. S. L. Week 3273 (U. S. Nov. 12, 1974) (No. 74-215).

[72] *Id.* at 841.

[73] *Id.* at 841, footnote 4.

[74] *Id.* at 842.

[75] *Id.* at 841.

[76] *Id.* at 840.

[77] *Id.* at 841-42.

[78] *Id.* at 841, footnote 3.

[79] *Id.* at 841, footnote 5.

[80] *Id.* at 841, footnote 3.

[81] *Id.*

[82] *Id.* at 841, footnote 5.

[83] *Id.* at 844.

[84] *United States v. Dotterweich, supra* note 2 at 285.

[85] See discussion in text at pages 18-19, *supra*.

[86] U. S. Supreme Court Transcript of Records, Vol. 11 at 164, *United States v. Dotterweich*, 320 U. S. 277 (1943).

[87] See *United States v. Kaadt, supra* note 31 at 604.

[88] See *United States v. Park, supra* note 71 at 844 (dissenting opinion).

[89] For published FDA guidelines, see generally FDA Regulatory Procedure Manual, Chapter 8-10, Regulatory Letters; Compliance Bulletin No. 70, April 12, 1972; Regulatory Procedure Manual, IV Legal-G, Transmittal Letters to U. S. Attorneys, November 15, 1966; FDA Inspector Operation Manual, Establishment Inspection: Evidence Development, Section 525, December 12, 1972; FDA Administrative Guidelines Manual, Guideline 7403.01, Chapter 3—Food Storage, January 1, 1973.

[90] Regulatory Procedure Manual, IV Legal-G, Transmittal Letters to U. S. Attorneys, at 5-6, November 15, 1966.

[91] See FDA Inspector Operation Manual, Establishment Inspection: Evidence Development, Section 525, December 12, 1972.

[92] *Id.*

[93] See Guideline 7403.01, Chapter 3—Food Storage, at 4-5, FDA Administrative Guidelines Manual, January 1, 1973.

[94] At least one instance is known where the Department of Justice refused to prosecute, that being a series of prescription drug advertising cases. See Rabin, *Agency Criminal Referrals in the Federal System: An Empirical Study of Prosecutorial Discretion,* 24 STAN. L. REV. 1036, 1067 (1972).

[95] *Id.* at 1091.

[96] *Id.* at 1042.

[97] Hearings on H. R. 15315 before Subcommittee on Public Health and Environment, Interstate and Foreign Commerce Committee, House of Representatives, 92d Cong. 2d Sess. (June 9, 1972) at pages 38-45.

[98] Rabin, *Agency Criminal Referrals in the Federal System: An Empirical Study of Prosecutorial Discretion, supra* note 94 at 1044-45.

[99] *Id.* at 1060.

[100] See FDA Ann. Rep. for years 1969-1973. Of the total of 352, 286 or 81.3% of cases brought involved foods, 50 or 14.2% involved drugs, 15 or 4.3% involved hazardous substances under the Federal Hazardous Substances Act, and 1 case involved a device. There were no cases involving cosmetics.

[101] *Id.*

[102] Letter from Mr. Sam Fine, FDA Associate Commissioner for Compliance, to presidents of food store chains, August 30, 1972.

[103] See *United States v. Morrissette,* 342 U. S. 246, 249-263 (1952).

[104] See *United States v. Moore,* 435 F. 2d 113 (D. C. Cir. 1970).

[105] *Id.*

[106] See Sayre, *Mens Rea,* 45 HARV. L. REV. 974 (1932) for a discussion of the complexities of the mental element in criminal offenses. See also Perkins, *Ignorance and Mistake in Criminal Law,* 88 U. PA. L. REV. 35 (1939).

[107] See Sayre, *Criminal Responsibility for Acts of Another,* 43 HARV. L. REV. 689 (1930) for a discussion of vicarious criminal liability. See also Dauphinais, *Vicarious Criminal Liability Under the Federal Food, Drug, and Cosmetic Act,* 11 FOOD DRUG COSM. L. J. 398 (1956).

[108] Sayre, *Mens Rea, supra* note 106 at 1020.

[109] See *United States v. Morrissette, supra* note 103; Sayre, *Public Welfare Offenses,* 33 COLUM. L. REV. 55 (1933) for a discussion of criminal public welfare offenses.

[110] *Id.* at 72-73.

[111] *Id.* at 68. See also *United States v. Dotterweich, supra* note 12.

[112] 258 U. S. 250 (1922).

[113] *Id.* at 252.

[114] *Id.*

[115] *Id.* at 254.

[116] Sayre, *Public Welfare Offenses, supra* note 109, at 68.

[117] *Id.* at 68, 78-84.

[118] Sayre, *Criminal Responsibility for Acts of Another, supra* note 107, at 702.

[119] *Id.* at 723.

[120] *Id.*

[121] Federal Food, Drug, and Cosmetic Act (hereinafter cited as the Act), 21 U. S. C. § 331 (1970).

[122] For a complete list of acts prohibited by the Federal Food, Drug, and Cosmetic Act, it is necessary to examine Section 301 (21 U. S. C. § 331 (1970)) (and Sections referred to therein), as well as Sections 402 and 403 (21 U. S. C. §§ 342, 343 (1970)) (enumerating acts constituting adulteration and misbranding of foods); Sections 501 and 502 (21 U. S. C. §§ 351, 352 (1970)) (enumerating acts constituting adulteration and misbranding of drugs and devices); and Sections 601 and 602 (21 U. S. C. §§ 361, 362 (1970)) (enumerating acts constituting adulteration and misbranding of cosmetics).

[123] The Act, § 302, 21 U. S. C. § 332 (1970).

[124] The Act, § 304, 21 U. S. C. § 334 (1970).

[125] For a discussion of the various enforcement mechanisms under the Act, see *Developments in the Law—The Federal Food, Drug, and Cosmetic Act,* 67 HARV. L. REV. 632, 673-720 (1954); *Symposium on Recalls,* 27 FOOD DRUG COSM. L. J. 332 (1972).

[126] The Act, § 303(a), 21 U. S. C. § 333(a) (1970).

[127] The Act, § 201(e), 21 U. S. C. § 321(e) (1970).

[128] The Act, § 303(b), 21 U. S. C. § 333(b) (1970).

[129] The Act, § 303(c), 21 U. S. C. § 333(c) (1970). For a discussion of the defenses, see *Developments in the Law—The Federal Food, Drug, and Cosmetic Act, supra* note 125, at 697-99.

[130] The Act, § 305, 21 U. S. C. § 335 (1970). For a discussion of Section 305 hearings, see Rissman, *Criminal Intent Under the Federal Food, Drug, and Cosmetic Act,* 7 FOOD DRUG COSM. L. J. 498 (1952), where at page 505 the issues in a Section 305 hearing are characterized as follows: "At this hearing the person heard may show that the violation was unavoidable; that the manufacturing procedures were careful, efficient and modern; that he was acting in accordance with administrative recommendations or educational programs; that continued research directed toward the improvement of procedure and controls is conducted; or anything else of a like nature. The Administrator may be satisfied that no advantage is to be gained from prosecution, and, consequently, he will not report the case. The public interest is thus adequately served by the notice and warning."

[131] The Act, § 306, 21 U. S. C. § 336 (1970).

[132] See Appendices I and II, item numbers A-1, A-2, B-1, C-1, C-2, C-3, C-4, C-5, C-6, C-7, C-8, D-1, E-1, F-1, G-1, J-1, J-2, J-3, J-4, J-5, L-1, L-2, N-1.

[133] See Appendices I and II, item numbers A-2, C-3, C-4, C-5, C-7, D-1, E-1, F-1, G-1, J-2, J-4, L-1, L-2.

[134] See Appendices I and II, item numbers A-1, B-1, C-1, C-2, C-6, C-8, J-1, J-3, J-5, N-1.

[135] See Appendices I and II, item number C-6.

[136] See Appendices I and II, item numbers A-1, C-2, J-3.

[137] See Appendices I and II, item numbers J-5, M-1.

[138] See Appendices I and II, item numbers A-1, A-2, B-1, C-1, C-2, C-3, C-4, C-5, C-6, C-7, C-8.

[139] See Appendices I and II, item numbers A-2, C-3, C-4, C-5, C-7.

[140] See Appendices I and II, item numbers A-1, B-1, C-1, C-2, C-6, C-8.

[141] See Appendices I and II, item number C-6.

[142] See Appendices I and II, item numbers A-1, C-2.

[143] See Appendices I and II, item numbers A-1, B-1, C-1, E-1, J-1, J-2.

[144] See Appendices I and II, item numbers A-2, C-2, C-3, C-4, C-5, C-6, C-7, C-8, D-1, F-1, G-1, J-3, J-4, J-5, L-1, N-1.

[145] See Appendices I and II, item numbers A-1, B-1, C-1.

[146] See Appendices I and II, item numbers A-2, C-2, C-3, C-4, C-5, C-6, C-7, C-8.

[147] See Appendices I and II, item number L-2.

[148] See Appendices I and II, item numbers D-1, E-1, F-1, G-1, L-1.

[149] See Appendices I and II, item numbers D-1, E-1, F-1, G-1, H-1, I-1, L-1, L-2.

[150] See Appendices I and II, item numbers D-1, E-1, F-1, L-1, L-2.

[151] See Appendices I and II, item numbers H-1, I-1.

[152] See Appendices I and II, item numbers D-1, E-1, F-1, J-1.

[153] See generally Austern, *Sanctions in Silhouette: An Inquiry into the Enforcement of the Federal Food, Drug, and Cosmetic Act,* 51 CALIF. L. REV. 38 (1963); *Developments in the Law—The Federal Food, Drug, and Cosmetic Act, supra* note 125; Dauphinais, *Vicarious Criminal Liability Under the Federal Food, Drug, and Cosmetic Act, supra* note 107; FINAL REPORT OF THE NATIONAL COMMISSION ON REFORM OF FEDERAL CRIMINAL LAWS, 75-76 (1971); Goldschmid, *An Evaluation of the Present and Potential Use of Civil Money Penalties as a Sanction by Federal Administrative Agencies,* 2 RECOMMENDATIONS AND REPORTS OF THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, 896 (July 1, 1970—December 31, 1972); Kadish, *The Crisis of Overcriminalization,* 374 Annals 157 (1967); Kadish, *Some Observations on the Use of Criminal Sanctions in Enforcing Economic Regulations,* 30 U. CHI. L. REV. 423 (1963); H. Packer, THE LIMITS OF THE CRIMINAL SANCTION, 354-63 (1968); PRESIDENT'S COMMISSION ON LAW ENFORCEMENT AND ADMINISTRATION OF JUSTICE TASK FORCE REPORT: THE COURTS, 97-107 (1967); Rissman, *Criminal Intent Under the Federal Food, Drug, and Cosmetic Act, supra* note 130; Sayre, *Criminal Responsibility for Acts of Another, supra* note 107; Sayre, *Public Welfare Offenses, supra* note 109; Smith and Pearson, *The Value of Strict Liability,* 1969 CRIM. L. R. 5.

[154] Sayre, *Criminal Responsibility for Acts of Another, supra* note 107 at 720.

[155] See discussion in text at pages 10-17, *supra.*

[156] *Id.*

[157] See discussion in text at pages 22-24, *supra.*

[158] See discussion in text at pages 20-24, *supra.*

[159] See discussion in text at pages 25-28, *supra.*

[160] See discussion in text at pages 31-33, *supra.*

[161] See discussion in text at pages 38-40, *supra.*

SUMMARY OF SURVEY OF FEDERAL HEALTH- OR SAFETY-RELATED STATUTES

Appendix II Item Number[2]	Name of Act	Year of Enactment[3]	Who Can Violate Act[4]	Civil Penalty Maximum Amount	Seizure	Injunction	Other Enforcement Tools	Criminal Penalty Maximum Amount[5]	Criminal Penalty Maximum Term[6]	Knowled Vicarious I Provide Statu
A	Federal Food, Drug, and Cosmetic Act	1938 1962	person	none	yes	yes	recall[7]	$1,000	one year	—statute is s both points —cases hold edge not a sary eleme —cases hold liability a ity
A-1	Filled Milk Act	1923	person	none	no	no	none	$1,000	one year	—statute sile knowledge —case holds edge not n —statute pro a form of liability
A-2	Imported Milk Act	1927 1940 1953	person	none	no	no	none	$2,000	one year	—statute req knowledge —statute sile vicarious l
B-1	Egg	1970	person	none	yes	yes	deten-	$1,000	one year	—statute is s

	Act									liability
C-2	Meat Inspection Act	1907 1967	person	none	yes	yes	detention	$1,000	one year	—statute is s knowledge —case holds edge not r —statute is vicarious
C-3	Diseased Livestock and Poultry Act 21 U. S. C. § 115	1884 1926 1928 1962	—railroad operators —vessel owners —persons in control of animals	none	no	no	no	$5,000	one year	—statute re knowledge —statute is vicarious
C-4	Animal Quarantine Act 21 U. S. C. § 122	1903	person	none	no	no	none	$1,000	one year	—statute re knowledg —statute is vicarious
C-5	Diseased Livestock and Poultry	1962	"whoever"	none	yes	yes	quarantine	$1,000	one year	—statute re knowledg —statute is vicarious

otes to Appendix I, see page 58

SUMMARY OF SURVEY OF FEDERAL HEALTH- OR SAFETY-RELATED STATUTE

Appendix II Item Number[2]	Name of Act	Year of Enactment[3]	Who Can Violate Act[4]	Civil Penalty Maximum Amount	Seizure	Injunction	Other Enforcement Tools	Criminal Penalty Maximum Amount[5]	Criminal Penalty Maximum Term[6]	Knowle Vicarious Provid Stat
C-6	Transportation of quarantined animals 21 U. S. C. § 124-127	1905 1928 1962	person	none	no	no	none	$1,000	one year	—statute is knowledg —case holds edge is re —statute is vicarious
C-7	Importation of diseased animals 21 U. S. C. § 104	1890	person	none	no	no	none	$5,000[9]	three years[8]	—statute re knowledg —statute is vicarious
C-8	Virus, Serum and Toxin Act	1913	person	none	no	no	none	$1,000	one year	—statute is knowledg —statute is vicarious

E-1	Federal Water Pollution Control Act	1948 1972	person[10]	$10,000 per day	no	yes	citizen suits	$25,000 per day	one year	—statute re wilfulnes gence for convictio for civil —statute pr that pers clude res corporate for purpo criminal
F-1	Clean Air Act	1955 1963 1965 1967 1970	person	$10,000	no	yes	citizen suits	$25,000	one year	—statute re knowledg criminal not for ci penalty —statute is vicarious
G-1	Consumer Product Safety Act	1972	person	$2,000 for each violation —maximum $500,000	yes	yes	citizen suits	$50,000	one year	—statute re knowledg penalty; can be *pr* from fact —for crimi tion, statu quires kn wilfulnes knowledg

SUMMARY OF SURVEY OF FEDERAL HEALTH- OR SAFETY-RELATED STATUTES

Appendix II Item Number[2]	Name of Act	Year of Enactment[3]	Who Can Violate Act[4]	Civil Penalty Maximum Amount	Seizure	Injunction	Other Enforcement Tools	Criminal Penalty Maximum Amount[5]	Criminal Penalty Maximum Term[6]	Knowledge Vicarious Lia Provided Statute
H-1	National Traffic and Motor Vehicle Safety Act	1966	person	$1,000 for each violation —maximum $400,000	no	yes	none	none	none	—statute is sile knowledge —statute is sile vicarious liab
I-1	Radiation Control for Health and Safety Act	1944 1968	person	$1,000 per violation —maximum $300,000	no	yes	none	none	none	—statute is sile knowledge —statute is sile vicarious liab
J-1	Economic Poison Control Act	1947 1959 1964 1970 1972	person	none	yes	no	none	$1,000	none for first offense	—statute is sile knowledge —statute provi a form of vic liability

			Private applicator or other person not included above	$1,000				$1,000	30 days	
J-3	Federal Hazardous Substances Act	1960 1966	person	none	yes	yes	none	$500	90 days	—statute is sil knowledge —statute is sil vicarious lia —case states k edge not nec
J-4	Flammable Fabrics Act	1953 1967	person	none	yes	yes	none	$5,000	1 year	—statute requi "wilfulness" criminal vio —statute is sil vicarious lia
J-5	Poison Prevention Packaging Act	1970	This Act employs the enforcement mechanism of the Hazardous Substances Act (See J-3) the Economic Poison Control Act (See J-1), and the Food, Drug, and Cosmetic Act (See A)							
K-1	Federal Aviation Act	1958	person	$1,000 per violation	none	none	Aircraft subject	none for safety	none for safety	—statute requi "knowledge wilfulness"

SUMMARY OF SURVEY OF FEDERAL HEALTH- OR SAFETY-RELATED STATUTE

Appendix II Item Number[2]	Name of Act	Year of Enactment[3]	Who Can Violate Act[4]	Civil Penalty Maximum Amount	Seizure	Injunction	Other Enforcement Tools	Criminal Penalty Maximum Amount[5]	Criminal Penalty Maximum Term[6]	Knowled Vicarious I Provide Statu
L-1	Occupational Safety and Health Act	1970	Employer	$10,000 if willful $1,000 if not	none	yes	citation	$10,000	6 months	—statute req knowledge ulness for violation —statute is vicarious l
L-2	Federal Coal Mine Health and Safety Act	1969	Coal mine operators	$10,000	none	yes	none	$25,000	1 year	—statute rec knowledge criminal v —statute se preclude v liability
M-1	Fair Packaging and Labeling Act	1966	person	none[11]	yes, if food, drug, cosmetic or device F, D	yes, if F, D, C, D Cease and desist order, if not	none	none	none	.....

N-1	Federal Trade Commission Act	1914 1938 1950	person	none[12]	none

For footnotes to Appendix I, see page 58.

yes, if F, D, C, D and false advertising cease and desist order, if not[12a]	none	$5,000 if violation is false advertising of F, D, D, D *and* product may be injurious to health *or* intent to mislead None, otherwise	six months, if violation is false advertising of F, D, C, D *and* product may be injurious to health *or* intent to mislead None, otherwise	—statute is silent on knowledge for criminal violation where product may be injurious to health —statute is silent on vicarious liability

FOOTNOTES TO APPENDIX I

[1] This summary is based on information set forth in more detail in Appendix II, attached.

[2] The item numbers correspond with the numbers in Appendix II.

[3] The year enactment of the statute. Where more than one year is noted, the additional years noted refer to years in which the statute was significantly amended.

[4] Where the term "person" is used, it includes individual, corporation, partnership, association, other business unit or similar phraseology—significant exceptions are noted.

[5] Based on penalties for first offenses related to public health or safety. Both criminal penalties can be imposed, unless otherwise indicated.

[6] *Id.*

[7] Recall is a remedy not expressly provided for in the Federal Food, Drug, and Cosmetic Act. See discussion in text of article at page 35.

[8] Either fine or imprisonment, but not both, may be imposed.

[9] The Comprehensive Drug Abuse Prevention and Control Act of 1970 is too complex to categorize. See Appendix II for a brief explanation.

[10] "Person" also includes states, municipalities, commissions and political subdivisions of states and interstate bodies. See 33 U. S. C. § 1362 (Supp. II, 1972).

[11] Each violation of a cease and desist order is subject to a civil penalty of $10,000.

[12] *Id.*

APPENDIX II

Personal Criminal Liability Under the Federal Food, Drug, and Cosmetic Act

The *Dotterweich* Doctrine

Survey of Federal Health- or Safety-Related Statutes

This appendix reports the results of a survey of twenty-seven federal statutes which relate to health or safety. In it we have sought briefly to define the basic objective of each statute, the nature of major violations of it, and the basic enforcement mechanism provided, with particular emphasis on criminal provisions and whether or not the concepts of absolute and vicarious liability are statutorily provided. We have also noted the dates of enactment and major amendments to the statutes.

This survey does not purport to be exhaustive of all federal health- or safety-related statutes, but efforts were made to report major legislation of this type.

It should be noted that, in some instances, the language of the statute itself makes it clear that knowledge of an act is a necessary element for criminal conviction. In other cases, the statute is silent on the question, as is the case in the Food, Drug, and Cosmetic Act. Where the statute is silent, we will note that knowledge is not a statutory element of a criminal offense. Obviously, the fact that a statute is silent does not necessarily mean that knowledge is not required. We have not examined legislative histories of the statutes surveyed nor have we made an in-depth study of case law arising under them. We have, however, noted relevant cases where they have come to our attention.

Nor have we discussed in depth for each statute the persons who, under the statutory language, may be held liable for a violation of it. In most instances the language of the statute provides that any "person" who violates a provision can be held liable. Many of the statutes expressly define "person," and those definitions have variously meant any individual, corporation, partnership, association, other business unit, or other similar designations. Many statutes simply provide that "whoever" violates the statute may be held liable. Only where the statutory definition of "person" materially differs from either of the above, or where a statute expressly provides that only a particular

For footnotes to Appendix II, see pages 76—78.

class of person (such as "employers" in the Occupational Safety and Health Act) may violate the statute, will we note the class of offender.

In reviewing the statutes, we will first report those which apply to the safety of foods, then drugs, then other products. We will then review other statutes designed to protect the public or segments of it from health or safety risks, closing with analysis of a few additional statutes of general interest.

A. *Statutes relating to milk and milk products*

(1) Under the Filled Milk Act,[1] enacted in 1923, any form of milk or cream, to which has been added any fat or oil other than milk fat so as to result in an imitation product, is deemed adulterated, and its manufacture or shipment in interstate commerce is unlawful. The penalty provided for violation is a maximum fine of $1,000 or imprisonment for a maximum of one year, or both. There is no statutory element of "knowledge," and the statute has been interpreted as not requiring knowledge as an essential element for criminal conviction of an individual defendant.[2]

The Filled Milk Act, unlike the Federal Food, Drug, and Cosmetic Act, provides for a form of vicarious liability by expressly providing that "the act, omission, or failure of any person acting for or employed by any individual, partnership, corporation, or association, within the scope of his employment or office, shall in every case be deemed the act, omission, or failure, of such individual, partnership, corporation, or association, as well as of such person."[3] It should be noted, of course, that this language does not expressly provide that corporate officers are personally liable for acts committed by their employees; rather this language expressly would hold a corporation so liable.

The constitutionality of the statute has been questioned on grounds not related to our discussion.[4]

(2) The importation into the United States of milk and cream without a permit issued by FDA is prohibited by 21 U. S. C. § 141, which was enacted in 1927. Inspections are authorized to assure that cows are healthy and that sanitary and healthful conditions prevail. Knowing violation of the provisions is punished by a fine of not more than $2,000 or by imprisonment for not more than one year, or both.

For footnotes to Appendix II, see pages 76—78.

B. *Statutes relating to eggs*

(1) The Egg and Egg Products Inspection Act,[5] enacted in 1970, is designed to protect the public health by helping to assure that eggs and egg products are wholesome, and properly labeled and packaged. The Secretary of Agriculture is authorized to inspect establishments which use eggs for human use and to condemn adulterated eggs and egg products. Products in violation of the Act may be detained up to twenty days, and are subject to seizure and condemnation proceedings and to injunction proceedings in court.

Violations of the Act are punishable by a maximum fine of $1,000, or imprisonment for up to one year, or both. Generally, no statutory element of knowledge or intent is present, except with respect to certain acts concerning counterfeit labeling and false statements, where knowledge is a statutory requirement.[6] If, however, a violation involves intent to defraud, the penalty is increased to a maximum fine of $10,000 and three years imprisonment, or both. Similarly, if the violation involves distribution or attempted distribution of adulterated articles, the penalty is increased to the level provided for intentional fraud, even though there is no statutory element of knowledge provided.[7] Adulteration is defined to include eggs or egg products (a) containing poisonous or deleterious substances rendering the article unfit for human food, (b) containing unsafe pesticide chemicals, food additives, or color additives, (c) packaged under insanitary conditions, (d) subjected to incubation, or (e) subjected to radiation.[8] If, however, the adulteration consists of substitution or omission of a constituent, or concealment of damage or inferiority, or if a substance has been added to increase the bulk or weight of the product or to reduce its quality or strength, or make it appear better than it is, the increased sanctions do not apply.[9]

The statute contains the same express provision concerning vicarious liability as is present in the Filled Milk Act.[10]

C. *Statutes relating to poultry and meat*

(1) The Poultry and Poultry Products Inspection Act,[11] enacted in 1957 and materially amended in 1968, is designed to protect the public health by helping to assure that poultry and poultry products are wholesome, and properly labeled and packaged. The Secretary of Agriculture is authorized to inspect establishments in which poultry is processed and he may quarantine and condemn adulterated poultry

For footnotes to Appendix II, see pages 76—78.

and poultry products. Poultry and poultry products in violation of the Act may be detained up to twenty days, and are subject to seizure and condemnation proceedings and injunctive proceedings in court.

Treatment of the element of knowledge, vicarious liability, and violations of the Act are the same as in the Egg and Egg Product Inspection Act, described above.[12]

(2) The Meat Inspection Act,[13] enacted in 1907 and substantially amended in 1967, is also similar to the egg and poultry inspection law. Its purpose is to protect the public health by helping to assure that meat and meat food products are wholesome, and properly labeled and packaged. The Secretary of Agriculture is authorized to inspect establishments in which meat is processed and he may condemn adulterated meat and meat products. Meat and meat products in violation of the Act may be detained up to twenty days, and are subject to seizure and condemnation proceedings and injunctive proceedings in court.

Treatment of the element of knowledge and violations of the Act are punishable in the same manner as violations of the egg and poultry inspection law described above.[14] However, in this case there is no statutory form of vicarious liability provided.

It is interesting to note that knowledge of the unlawfulness of a prohibited act under the Meat Inspection Act was not held necessary in *United States v. Hart Motor Express, Inc.*[15] In that case, a corporate defendant lost a motion to dismiss a portion of the information charging that an employee detached an official seal of the Secretary of Agriculture. Defendant corporation argued that the allegation was insufficient in that it failed to allege that defendant "knowingly" detached the seal. Noting the absence of the words "knowingly or wrongfully" in the statutory language defining detaching an official seal as an unlawful act, and noting the presence of those words in the definition of other prohibited acts, the court held that *scienter* was not an element in the offense.

(3) The transportation of diseased and quarantined animals and poultry is regulated under several different provisions of Title 21 of the United States Code. Section 115, enacted in 1884, and amended in 1926, 1928, and 1962, makes it unlawful for a person to deliver for transport or to transport livestock or live poultry which is affected by any contagious disease. Violation is punished by a maximum fine

For footnotes to Appendix II, see pages 76—78.

of $5,000 and one year in prison, or both. Knowledge is a statutory element of the offense.

The Act may be violated by "any person or persons operating" a railroad or by any "master or owner of any boat or vessel," or by the "owner or custodian of or person having control over" the animals.[16]

(4) Section 122 of Title 21, enacted in 1903, provides a penalty of no more than $1,000 or one year in prison, or both, for any person knowingly to violate Sections 111, 120, 121, or orders or regulations issued thereunder. These sections authorize the Secretary to make regulations to prevent the dissemination of contagious diseases of animals and live poultry, and to regulate the exportation and transportation of such animals.

(5) In order to help protect the public from diseased livestock or poultry, the Secretary of Agriculture is authorized to quarantine such animals, to regulate transportation vehicles as to sanitary conditions, to regulate the movement of animals which may be diseased, and to inspect carriers of animals.[17] Penalties for knowing violation of a regulation are a maximum fine of $1,000 or imprisonment for one year, or both. Seizures and injunctions may also be sought. These provisions were enacted in 1962.

(6) The transportation of quarantined animals or live poultry is also prohibited by a law enacted in 1905.[18] Violation is punishable by a maximum fine of $1,000 or one year in prison, or both.[19] Though there is no statutory element of knowledge, a District Court in Missouri held in 1910 that "guilty knowledge" was required to hold a railroad criminally liable for violation of a government regulation issued under the Act.[20]

(7) The importation of diseased animals, or those which have been exposed to disease within sixty days prior to their export, is unlawful under a statute enacted in 1890.[21] Penalty for knowing violation is a maximum fine of $5,000 or imprisonment for three years, but *not both*. Transportation vehicles may also be forfeited to the government.

(8) The manufacture, shipment and import of viruses, serums, and toxins intended for use in treatment of domestic animals is prohibited without a permit issued by the Secretary of Agriculture, and in accord with his regulations.[22] Violation of this 1913 statute is punishable by a maximum fine of $1,000 or imprisonment for one year, or both. No statutory element of intent or knowledge is present.

For footnotes to Appendix II, see pages 76—78.

D. *Statutes relating to drug abuse control*

(1) The Comprehensive Drug Abuse Prevention and Control Act of 1970[23] establishes a series of classifications for drugs, and other substances, based on their potential for abuse, safety, and medical use. The degree of "control," administered by the Attorney General, varies according to the abuse potential and other factors as set forth in the Act, including such controls as production quotas and recordkeeping requirements for manufacturers, wholesalers and retailers.

The penalties prescribed by the Act are very sophisticated and precise, varying according to the classification of the drug, the offender, and the nature of the violation. For example, "knowing or intentional" manufacture, possession, or distribution in violation of the Act of a controlled substance, in Schedule I or II (the most "controlled" substances), which is a narcotic drug, can result in a maximum penalty of up to fifteen years in prison, and a fine of up to $25,000 or both. If the substance is not a narcotic or is in Schedule III, the maximum penalty is five years and a fine of $15,000 or both. If the substance is in Schedule IV, the maximum penalty is three years and a fine of $10,000 or both. If the substance is in Schedule V, the maximum penalty is one year imprisonment and a fine of $5,000, or both. In all cases, second convictions double the penalty and special parole term requirements are imposed, except in the case of Schedule V substances.[24]

Any person eighteen years old or older who "knowingly or intentionally" distributes a controlled substance in violation of the Act, to a person under twenty-one is subject to twice the penalties described in the previous paragraph. If the offense results in a second conviction, the penalties are triple those described in the previous paragraph.[25]

Dispensing a controlled substance to the ultimate user in violation of the Act, or dispensing such a substance without labeling required by the Act, or to manufacture a controlled substance in excess of established quotas, *inter alia*, can result in a civil penalty of up to $25,000. If the violation is "knowingly" committed, the penalty becomes criminal with a maximum penalty of one year in prison and a fine of $25,000 or both. A second conviction doubles the penalty.[26]

"Knowing or intentional" distribution of a Schedule I or II substance (except pursuant to an order as required), or use of a fictitious registration number, or obtaining a controlled substance by

For footnotes to Appendix II, see pages 76—78.

misrepresentation, *inter alia,* can result in a prison sentence of up to four years and a fine of $30,000 or both. Second convictions double the penalty.[27]

"Knowing or intentional" possession of a controlled substance in violation of the Act can result in imprisonment for not more than one year and a fine of up to $5,000 or both. Second convictions double the penalty. In the case of first offenders, the court may place the offender on probation without entering a judgment of guilty. At the conclusion of probation, offenders under twenty-one may apply to the court for an order expunging all official records.[28]

"Knowing or intentional" import or export of a controlled substance, or possession of such aboard a vessel, aircraft or vehicle in violation of the Act, or manufacture or distribution of a Schedule I or II controlled substance, intending or knowing that such substance unlawfully will be imported into the United States, can result in fifteen years imprisonment or a $25,000 fine, or both, if the violation is with respect to a narcotic drug. If the violation is with respect to a non-narcotic drug, the maximum penalty is five years, or $15,000, or both. There are provisions for special parole terms as well.[29]

While the above discussion is not exhaustive of the penalties provided for violation of the Act, they are the major ones. Other penalties are provided for conspiracy,[30] continuing conspiracy,[31] commission of offenses by "dangerous special drug offenders,"[32] transshipment of controlled substances,[33] and other miscellaneous matters. In each case where an unlawful act is defined, however, the element of knowledge or intent is a statutory element of a criminal offense. Knowledge or intent is not necessary where a civil penalty is prescribed. The statute is silent as to vicarious liability.

Other enforcement tools available under the Act include forfeiture of raw material, controlled substances, transportation vehicles and records,[34] and injunctions.[35] There is also a provision which states "before any violation . . . is reported . . . for institution of a criminal proceeding, the Director may require that the person against whom such proceeding is contemplated be given appropriate notice and an opportunity to present his views. . . ."[36]

E. *Statutes related to water pollution*

(1) The Federal Water Pollution Control Act,[37] enacted in 1948 and substantially amended in 1972, sets forth a comprehensive pro-

For footnotes to Appendix II, see pages 76—78.

gram of legislation designed to restore and maintain the integrity of the nation's waters. Subchapter III[38] sets forth requirements for discharging pollutants in the nation's waters in order to protect water quality, provide a proper environment for fish and wildlife and allow for recreational activities. The Environmental Protection Agency (EPA) is authorized to issue water quality standards, regulate the discharge of pollutants and regulate ocean dumping.

Among the enforcement mechanisms provided for in the Act are civil actions and temporary and permanent injunctions.[39] Citizen suits are also authorized.[40] A maximum civil penalty of $10,000 per day is provided for any person who violates the Act[41] and criminal penalties for persons "willfully or negligently" violating the Act are provided in the amount of not less than $2,500 nor more than $25,000 per day, or imprisonment for one year, or both. Any person who knowingly makes a false statement may be fined not more than $10,000 or six months imprisonment, or both.[42] For purposes of criminal prosecution, "person" is specifically defined to include "any responsible corporate officer."[43]

F. *Statutes relating to air pollution*

(1) The Clean Air Act,[44] enacted in 1955 and substantially amended in 1963, 1965, 1967, and 1970, sets forth comprehensive legislation designed to protect the public from hazards associated with polluted air.

There are numerous and complex requirements and procedures applicable to both state and private sources of air pollutants. Generally, knowing violation of requirements under the Act is punishable by a fine of not more than $25,000 per day, or by imprisonment of not more than one year, or both, and a second conviction doubles the penalty.[45] Also, injunction and other "appropriate relief" is authorized.[46]

Subchapter II of the Clean Air Act sets forth provisions relating to air pollutant emissions.[47] This provision authorizes the Environmental Protection Agency to issue standards for emission of air pollutants by motor vehicles to protect the public health.

Any person who violates standards issued under Subchapter II is subject to a civil penalty of not more than $10,000. In some cases, a violation with respect to each motor vehicle can constitute a separate offense.[48]

For footnotes to Appendix II, see pages 76—78.

Private citizens are permitted, under certain circumstances, to institute civil actions against anyone alleged to be in violation of emission standards and certain other provisions of the Act, as well as against the EPA where a failure to perform a mandatory duty under the Act is alleged.[49]

G. *Statutes relating to consumer products*

(1) The Consumer Product Safety Act,[50] enacted in 1972, has as its primary purpose the protection of the public against unreasonable risks of injury associated with consumer products. The Act establishes a Consumer Product Safety Commission empowered to issue uniform safety standards for consumer products and to ban unreasonably hazardous consumer products from the marketplace.

The enforcement mechanism of the Act provides for injunction and seizure of violative products,[51] suits for damages by persons injured as a result of violations of product safety rules or regulations issued by the Commission,[52] suits by private citizens to enforce safety rules or Commission orders,[53] and retention of private remedies at common law or under State statutes.[54] A civil penalty not to exceed $2,000 can be assessed against any person who knowingly violates the Act, including manufacturing, offering for sale, or distributing any product not in conformity with an applicable standard or declared a banned hazardous product, or failing to furnish certain information or to comply with certain rules.[55] The statute is unusual in that it requires a *knowing* violation for a *civil* penalty. "Knowingly" is expressly defined as "(1) the having of actual knowledge, or (2) the presumed having of knowledge deemed to be possessed by a reasonable man who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations."[56] In certain cases, a separate offense is committed with respect to each consumer product involved, with a maximum penalty of $500,000 for a related series of violations.[57]

Criminal penalties are assessed against persons who *knowingly and willfully* violate the Act *after* receiving a notice of noncompliance from the Commission. Violators may be fined not more than $50,000 or imprisoned for not more than one year, or both.[58] Any individual director, officer, or agent of a corporation who knowingly and willfully violates the Act and who has knowledge of a notice of noncompliance received by the corporation is similarly criminally liable.[59]

For footnotes to Appendix II, see pages 76—78.

H. *Statutes relating to automobile safety*

(1) The National Traffic and Motor Vehicle Safety Act of 1966[60] is designed to reduce traffic accidents and deaths and injuries to persons resulting therefrom. The Secretary of Transportation is authorized to establish motor vehicle and motor vehicle equipment safety standards. It is unlawful for any person to manufacture, sell, or offer for sale substandard vehicles or equipment, to refuse access to records, to fail to make reports, to fail to provide information or permit inspection, to fail to issue certificates, or to fail to furnish notice of defects, all as required by the Act.[61] Violation of the above provisions, or of any regulation issued thereunder, is subject to a maximum civil penalty of $1,000 per violation. Violation with respect to each automobile or item of equipment constitutes a separate violation, and the maximum civil penalty for any related series of violations is $400,000.[62] The Attorney General also is authorized to seek injunctive relief to restrain violations and the Secretary of Transportation is required, whenever practicable, to notify a person against whom injunctive relief is contemplated, and afford him an opportunity to present his views, and, except in a case of knowing and willful violation, afford him reasonable opportunity to achieve compliance.[63]

I. *Statutes relating to radiation from electronic products*

(1) The Radiation Control for Health and Safety Act,[64] enacted in 1944 and substantially amended in 1968, is designed to protect the public health and safety from the dangers of electronic product radiation through the development and administration of performance standards issued by the Secretary of Health, Education and Welfare to control the emission of radiation from the regulated products.

Introduction or delivery of products in violation of standards, failure to furnish notification, or to maintain records, or permit access to records, or to make reports, or to issue certificates all as required by the Act, is unlawful.[65]

The enforcement mechanism of the Act gives jurisdiction to the district courts of the United States to restrain violations of the Act,[66] and provides civil penalties for violation of not more than $1,000 per violation, with a $300,000 limit on any related series of violations.[67]

For footnotes to Appendix II, see pages 76—78.

J. *Statutes relating generally to hazardous substances*

(1) The Economic Poison Control Act,[68] enacted in 1947 and amended in 1959, 1964, 1970 and 1972, regulates "economic poisons" generally defined as substances intended to destroy various plant and animal life.[69]

The Act is administered by the Environmental Protection Agency. Any person who distributes, sells, offers for sale, ships, or delivers for shipment, an unregistered economic poison is guilty of a misdemeanor and may be fined not more than $1,000.[70] Any person violating any other provision of the Act, including the misbranding and adulteration sections, is guilty of a misdemeanor and fined not more than $500 for a first offense, and, for subsequent offenses is fined not more than $1,000, or imprisoned for not more than one year, or both, provided that an offense committed more than five years after the last conviction is considered a first offense.[71]

This Act also expressly provides that the act or omission of any officer, agent, or other person acting for or employed by any person shall also be deemed to be the act or omission of the employer.[72] This provision is similar to that in the Filled Milk Act and the Egg Product Inspection Act.

Seizure is also authorized.[73]

(2) The Environmental Pesticide Control Act,[74] enacted in 1947 and substantially amended in 1972, is designed to control the use of pesticides by applicators and thereby protect public safety. The Environmental Protection Agency is authorized to register and classify pesticides and to control their use.

The enforcement mechanism of the Act provides for "stop sale or removal" orders issued by the Administrator,[75] seizure,[76] and civil and criminal penalties.[77] Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of the Act may be assessed a civil penalty by the Administrator of not more than $5,000 for each violation.[78] Private applicators and others who violate the Act after receiving a written warning or citation for a prior violation may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense.[79] Notice and opportunity for hearing are required before assessment of civil penalties and the Administrator is to consider, in determining the amount of the penalty, the seriousness of the violation, the size of the business and the effect on its ability to continue.[80]

For footnotes to Appendix II, see pages 76—78.

Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who "knowingly" violates any provision of the Act is guilty of a misdemeanor and, upon conviction, fined not more than $25,000 or imprisoned for not more than one year, or both.[81] In the case of private applicators or other persons, the fine is not to exceed $1,000 or imprisonment for not more than 30 days, or both.[82] As with the Economic Poison Control Act, the act or omission of any person acting for or employed by another is also considered the act of such other person.[83]

(3) The Federal Hazardous Substances Act,[84] enacted in 1960 and amended in 1966, regulates "hazardous" substances in interstate commerce. Generally, these substances include, with specific exceptions, flammable and toxic substances, and irritants, and those which may cause "substantial personal injury or substantial illness" as a result of foreseeable use. The Consumer Product Safety Commission[85] is authorized to issue regulations declaring substances hazardous under the Act.[86] Hazardous substances are required to meet certain label requirements,[87] and in certain circumstances, products may be banned from commerce.[88]

The enforcement mechanism of the Act provides for injunction,[89] seizure,[90] and criminal penalties.[91] The Act provides that any person who commits any of the prohibited acts including the giving of a false guaranty and the introduction into interstate commerce of any misbranded substance, is guilty of a misdemeanor and subject to a fine of not more than $500 or imprisonment for not more than 90 days, or both.[92] For a second offense or for offenses committed with intent to defraud or mislead, the penalty is a fine of not more than $3,000 or imprisonment for not more than one year, or both.[93] There are limited defenses for receipts or deliveries made in good faith or under a guaranty.[94]

While there is no statutory element of knowledge, a U. S. District Court has interpreted the Act as not requiring "knowledge and willfulness."[95]

(4) The Flammable Fabrics Act,[96] enacted in 1953 and substantially amended in 1967, seeks to control the movement in interstate commerce of wearing apparel or fabric which are so highly flammable as to be dangerous. The Consumer Product Safety Commission[97] may issue standards and regulations necessary to that end.

For footnotes to Appendix II, see pages 76—78.

The enforcement mechanism of the Act provides for injunction and condemnation proceedings.[98] Any person who "willfully" manufactures or puts into interstate commerce a violative fabric or gives a false guaranty is guilty of a misdemeanor and may be fined not more than $5,000 or imprisoned for not more than one year, or both.[99] Any person who knowingly gives a false guaranty is guilty of an unfair method of competition and unfair or deceptive act or practice under the Federal Trade Commission Act.[100]

(5) The Poison Prevention Packaging Act of 1970[101] authorizes the Consumer Product Safety Commission[102] to establish standards for the special packaging of certain household substances in order to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances. The Act covers hazardous substances, pesticides, foods, drugs, and cosmetics, as well as other substances.[103] Violation of a packaging standard constitutes a misbranding violation of the substantive Act covering the substance involved.[104] Thus, for example, if a drug is packaged in violation of the Poison Prevention Packaging Act, it is misbranded under the Federal Food, Drug, and Cosmetic Act and the enforcement mechanisms of the latter Act apply.

Therefore, the identical act can be punished more severely in one instance than in another, depending upon which statute controls. If the substance is covered by the Federal Hazardous Substances Act, the maximum criminal penalty is no more than a $500 fine or a ninety-day sentence, or both. If the substance is covered by the Food, Drug, and Cosmetic Act, criminal penalties are a maximum of $1,000 or one year, or both. If the Economic Poisons Act is involved, there can be no imprisonment for a first offense, and the maximum criminal fine is $1,000.

K. *Statutes relating to airplane safety*

(1) The Federal Aviation Act,[105] enacted in 1958, deals broadly with air transportation. Portions of it relate directly to public safety through regulation of air traffic control and airplane safety. These portions are administered by the Federal Aviation Administrator.[106] The Administrator is authorized, *inter alia,* to prescribe minimum standards governing the design, performance, and construction of aircraft, aircraft engines, and propellers; to provide rules for inspection, ser-

For footnotes to Appendix II, see pages 76—78.

vicing, and overhaul of the aircraft engines, propellers, and appliances; to provide rules for hours of service for employees; and to provide other rules necessary to provide safety in air commerce.[107] The Administrator also is authorized, after proper testing, to issue certificates to airmen[108] and aircraft.[109] It is unlawful for any person to operate an air carrier in violation of any rule, regulation, or certificate under this subchapter.[110]

Any person who violates this portion of the Act is subject to a civil penalty not to exceed $1,000 for each violation.[111] If violation is a continuing one, each day constitutes a separate offense.[112] If the person charged is the owner of, or in command of, the aircraft involved, the aircraft is subject to lien for the penalty.[113]

There is no criminal penalty for violation of these provisions, although criminal penalties are provided for "knowing and willful" violations of some other parts of the Act.[114]

L. *Statutes related to occupational health and safety*

(1) The Occupational Safety and Health Act of 1970[115] authorizes the Secretary of Labor to set mandatory occupational safety and health standards for businesses affecting interstate commerce. If, after inspection or investigation, the Secretary believes an employer has violated any standard or requirement under the Act, he issues a citation to the employer, sets a reasonable time for abatement of the violation, and may assess a penalty.[116] The employer has fifteen days to contest the citation and penalty. If he does not do so, the order is final and not subject to review. If the employer contests the citation or penalty, the Secretary notifies the Occupational Safety and Health Review Commission established by the Act.[117] The Commission affords opportunity for hearing and issues its findings and order regarding the citation and penalty. The Commission's order is appealable to the Court of Appeals.[118]

Any "employer" (defined in the Act as meaning "a person engaged in a business affecting commerce who has employees . . .")[119] who "willfully or repeatedly" violates the Act or any order or standard issued under the Act may be assessed a civil penalty of not more than $10,000 for each violation. An employer who has received a citation for a "serious violation" (defined as one presenting a sub-

For footnotes to Appendix II, see pages 76—78.

stantial probability of death or serious physical harm)[120] shall be assessed a civil penalty of up to $1,000 for each violation. An employer who fails to correct a violation for which a citation has been issued within the period permitted by a final order for its correction, may be fined a civil penalty of not more than $1,000 for each day during which such failure or violation continues. An employer who "willfully" violates an order or standard, and that violation causes death to any employee, upon conviction shall be fined up to $10,000 or six months imprisonment, or both. The penalty is doubled for second convictions. Whoever "knowingly" makes a false statement, representation, or record can be fined $10,000 and imprisoned for six months. Employers who fail to post required notices under the Act are assessed a civil penalty of up to $1,000 for each violation. There is no statutory element of knowledge required for this last violation.[121]

(2) The Federal Coal Mine Health and Safety Act of 1969[122] authorizes the Secretary of the Interior and the Secretary of Health, Education and Welfare to set mandatory health and safety standards to protect coal miners.

The Secretary of the Interior may institute civil actions for relief, including temporary or permanent injunctions and restraining orders for violations. Attorneys appointed by the Secretary may represent him, subject to the direction and control of the Attorney General.[123]

Violations of the Act by mine operators can result in a civil penalty assessed by the Secretary of up to $10,000 for each occurrence of a violation. While there is no statutory element of knowledge, the Secretary is to consider, in assessing a penalty, the operator's history of violations, the appropriateness of the penalty to the size of the operator's business, whether he was negligent, the gravity of the violation, and the operator's good faith in correcting the violation. Civil penalties may be assessed only after the operator is given the opportunity for a public hearing. "Willful" violation of a mandatory health or safety standard and "knowing" violation of specified orders is punishable by a maximum fine of $25,000 or one year imprisonment, or both. Second conviction doubles the fine and the possible prison term is extended to five years. Knowing false statements are punishable by a maximum fine of $10,000 and six months imprisonment, or both.[124]

For footnotes to Appendix II, see pages 76—78.

The Act expressly provides that "whenever a corporate operator violates a mandatory health or safety standard or knowingly violates or fails" to comply with an order, "any director, officer, or agent of such corporation, who knowingly authorized, ordered, or carried out such violation, failure, or refusal shall be subject to" the civil or criminal penalties provided under the Act.[125] This would seem to preclude any vicarious liability in the corporate area.

M. *Statute relating to fair packaging and labeling*

(1) The Fair Packaging and Labeling Act[126] (FPLA), enacted in 1966, is intended to enable consumers to obtain accurate information as to the quantity of the contents of packaging and facilitate value comparisons.

The Act regulates labeling by requiring that the label bear, *inter alia,* the identity of the commodity, the name and place of business of the manufacturer, packer, or distributor, and the net quantity of contents.[127]

The Secretary of Health, Education and Welfare is authorized under the Act to promulgate regulations with respect to foods, drugs, devices, or cosmetics, while the Federal Trade Commission is authorized to do so with respect to other consumer commodities as defined in the Act.[128] Packaging and labeling not conforming to provisions of the Act or regulations promulgated under it are prohibited.[129]

Enforcement is provided by means of a cease and desist order as provided under Section 45(b)[130] of the Federal Trade Commission Act, for consumer commodities other than foods, drugs, devices and cosmetics.[131] Foods, drugs, devices, or cosmetics which are in violation of the Act or a regulation under it are deemed misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and are subject to seizure and injunction. However, the criminal penalties generally available under the Food, Drug, and Cosmetic Act are expressly not available for violation of the FPLA.[132] Whether or not a food, drug, device, cosmetic, or other consumer commodity is involved, there is no statutory element of intent.

N. *Statutes relating to fair trade practices*

(1) The Federal Trade Commission Act,[133] enacted in 1914, and substantially amended in 1938 and 1950, creates the Federal Trade

For footnotes to Appendix II, see pages 76—78.

Commission to regulate industry practices in order to help prevent unfair methods of competition and false advertising.

To this end the Act declares unlawful, unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce.[134] Whenever the Commission has reason to believe that any such methods or acts have been used, the Commission issues a complaint and notice and holds a hearing in respect thereof. If the Commission is of the opinion that the act or practice is prohibited, it issues an order requiring the person, partnership, or corporation involved to cease and desist from using such method of competition or such act or practice.[135] Provision for review of the order in the Courts of Appeal in the United States is provided.[136] Any person, partnership, or corporation who violates a cease and desist order after it has become final is subject to a civil penalty of not more than $10,000 for each violation. Each separate violation of such order is a separate offense, and in the case of a violation through continuing failure or neglect to obey, each day of continuance of such failure or neglect is deemed a separate offense.[137]

The Act also provides that the dissemination of false advertising likely to induce the purchase of food, drugs, devices, or cosmetics is unlawful and constitutes an unfair or deceptive act or practice.[138] When the Commission believes that such advertising is about to occur, it may seek a temporary injunction in a district court.[139] A criminal penalty of a fine of not more than $5,000, or imprisonment for not more than six months, or both, can be imposed on any person, partnership, or corporation who violates this prohibition against false advertising if use of the commodity advertised may be injurious to health or if the violation is with intent to defraud or mislead.[140] Stiffer penalties are provided for second convictions.[141] There is no statutory element of intent.

Thus, this statute, which is intended to protect the public more from an economic, rather than a health, standpoint, does not rely heavily on criminal enforcement. Only in the area of false advertising where there is a threat to health or a wrongful intent are criminal penalties assessed.

For footnotes to Appendix II, see pages 76—78.

FOOTNOTES TO APPENDIX II

[1] 21 U. S. C. § 61 (1970).

[2] See *United States v. Carolene Products Co.*, 51 F. Supp. 675, 680 (D. W. Va. 1943), *aff'd* 140 F. 2d 61 (4th Cir. 1944), *aff'd* 323 U. S. 18 (1944). The District Court, however, found the individual defendants knew that the company was shipping the questioned product in interstate commerce.

[3] 21 U. S. C. § 63 (1970).

[4] Compare *Milnot Co. v. Richardson*, 350 F. Supp. 221 (S. D. Ill. 1972) with *United States v. Carolene Products Co.*, 304 U. S. 144 (1938) and *United States v. Carolene Products Co., supra* note 2.

[5] 21 U. S. C. § 1031 (1970).

[6] 21 U. S. C. § 1037 (d) (5)-(7) (1970).

[7] 21 U. S. C. § 1041 (a) (1970).

[8] 21 U. S. C. § 1033 (a) (1970).

[9] 21 U. S. C. § 1041 (1970).

[10] 21 U. S. C. § 1041 (a) (1970).

[11] 21 U. S. C. § 451 (1970).

[12] 21 U. S. C. § 461 (1970).

[13] 21 U. S. C. § 601 (1970).

[14] 21 U. S. C. § 676 (1970).

[15] 160 F. Supp. 886 (D. Minn. 1958).

[16] 21 U. S. C. § 117 (1970).

[17] 21 U. S. C. § 134a (1970).

[18] 21 U. S. C. §§ 124, 126 (1970).

[19] 21 U. S. C. § 127 (1970).

[20] See *United States v. Chicago B. & O. R. Co.*, 181 Fed. 882 (D. Mo. 1910).

[21] 21 U. S. C. § 104 (1970).

[22] 21 U. S. C. § 151 (1970).

[23] 21 U. S. C. § 801 (1970).

[24] 21 U. S. C. § 841 (1970).

[25] 21 U. S. C. § 845 (1970).

[26] 21 U. S. C. § 842 (1970).

[27] 21 U. S. C. § 843 (1970).

[28] 21 U. S. C. § 844 (1970).

[29] 21 U. S. C. § 960 (1970).

[30] 21 U. S. C. §§ 846, 963 (1970).

[31] 21 U. S. C. § 848 (1970).

[32] 21 U. S. C. § 849 (1970).

[33] 21 U. S. C. §§ 954, 961 (1970).

[34] 21 U. S. C. § 881 (1970).

[35] 21 U. S. C. § 882 (1970).

[36] 21 U. S. C. § 883 (1970).

[37] 33 U. S. C. § 1251 (Supp. II, 1972).

[38] 33 U. S. C. § 1311 (Supp. II, 1972).

[39] 33 U. S. C. § 1319 (b) (Supp. II, 1972).

[40] 33 U. S. C. § 1365 (Supp. II, 1972).

[41] 33 U. S. C. § 1319 (d) (Supp. II, 1972). Compare 33 U. S. C. § 1415 (a) (Supp. II, 1972), which provides a maximum civil penalty of $50,000 for a violation of provisions relating to dumping materials in ocean waters.

[42] 33 U. S. C. § 1319 (c) (Supp. II, 1972). Compare 33 U. S. C. § 1415 (b) (Supp. II, 1972), which provides a maximum criminal penalty for "knowing" violation of ocean dumping provisions of up to $50,000 or one year in prison, or both.

[43] 33 U. S. C. § 1319 (c) (3) (Supp. II, 1972).

[44] 42 U. S. C. § 1857 (1970).

[45] 42 U. S. C. § 1857c-8(c) (1970).
[46] 42 U. S. C. §1857c-8(b) (1970).
[47] 42 U. S. C. § 1857f (1970).
[48] 42 U. S. C. § 1857f-4 (1970). Compare 42 U. S. C. § 1857f-6c (d) (1970), which provides a civil penalty of $10,000 for each day of each violation of fuel provisions of the Act.
[49] 42 U. S. C. § 1857h-2 (1970).
[50] 15 U. S. C. § 2051 (Supp. II, 1972).
[51] 15 U. S. C. § 2071 (Supp. II, 1972).
[52] 15 U. S. C. § 2072 (Supp. II, 1972).
[53] 15 U. S. C. § 2073 (Supp. II, 1972).
[54] 15 U. S. C. § 2074 (Supp. II, 1972).
[55] 15 U. S. C. § 2069 (Supp. II, 1972).
[56] 15 U. S. C. § 2069(c) (Supp. II, 1972).
[57] 15 U. S. C. § 2069(a) (Supp. II, 1972).
[58] 15 U. S. C. § 2070(a) (Supp. II, 1972).
[59] 15 U. S. C. § 2070(b) (Supp. II, 1972).
[60] 15 U. S. C. § 1381 (1970).
[61] 15 U. S. C. § 1397 (1970).
[62] 15 U. S. C. § 1398 (1970).
[63] 15 U. S. C. § 1399 (1970).
[64] 42 U. S. C. § 263b (1970).
[65] 42 U. S. C. § 263j (1970).
[66] 42 U. S. C. § 263k (a) (1970).
[67] 42 U. S. C. § 263k (b) (1) (1970).
[68] 7 U. S. C. § 135 (1970).
[69] 7 U. S. C. § 135 (a) (1970).
[70] 7 U. S. C. § 135 f (a) (1970).
[71] 7 U. S. C. § 135 f (b) (1970).
[72] 7 U. S. C. § 135 f (d) (1970).
[73] 7 U. S. C. § 135 g (1970).
[74] 7 U. S. C. § 136 (Supp. II, 1972).
[75] 7 U. S. C. § 136 k (a) (Supp. II, 1972).
[76] 7 U. S. C. § 136 k (b) (Supp. II, 1972).
[77] 7 U. S. C. § 136 l (Supp. II, 1972).
[78] 7 U. S. C. § 136 l (a) (1) (Supp. II, 1972).
[79] 7 U. S. C. § 136 l (a) (2) (Supp. II, 1972).
[80] 7 U. S. C. § 136 l (a) (3) (Supp. II, 1972).
[81] 7 U. S. C. § 136 l (b) (1) (Supp. II, 1972).
[82] 7 U. S. C. § 136 l (b) (2) (Supp. II, 1972).
[83] 7 U. S. C. § 136 l (b) (4) (Supp. II, 1972).
[84] 15 U. S. C. § 1261 (1970).
[85] 15 U. S. C. § 2079 (a) (Supp. II, 1972).
[86] 15 U. S. C. § 1262 (1970).
[87] 15 U. S. C. § 1261 (p) (1970).
[88] 15 U. S. C. § 1261 (q) (1970).
[89] 15 U. S. C. § 1267 (1970).
[90] 15 U. S. C. § 1265 (1970).
[91] 15 U. S. C. § 1264 (1970).
[92] 15 U. S. C. § 1264 (a) (1970).
[93] *Id.*
[94] 15 U. S. C. § 1264 (b) (1970).
[95] See *United States v. Chalaire*, 316 Fed. Supp. 543, 548 (E. D. Louisiana 1970).
[96] 15 U. S. C. § 1191 (1970).
[97] 15 U. S. C. § 2079 (b) (Supp. II, 1972).

[98] 15 U. S. C. § 1195 (1970).
[99] 15 U. S. C. § 1196 (1970).
[100] 15 U. S. C. § 1197 (b) (1970).
[101] 15 U. S. C. § 1471 (1970).
[102] 15 U. S. C. § 2079 (Supp. II, 1972).
[103] 15 U. S. C. §§ 1471, 1472 (1970).
[104] See 15 U. S. C. § 1261 (p) (1970); 7 U. S. C. § 135 (z)(i) (1970); 21 U. S. C. §§ 343 (n), 352 (p), 362 (f) (1970).
[105] 49 U. S. C. § 1301 (1970).
[106] 49 U. S. C. § 1655 (c) (1970).
[107] 49 U. S. C. § 1421 (1970).
[108] 49 U. S. C. § 1422 (1970).
[109] 49 U. S. C. § 1423 (1970).
[110] 49 U. S. C. § 1430 (1970).
[111] 49 U. S. C. § 1471 (1970).
[112] *Id.*
[113] *Id.*
[114] See 49 U. S. C. § 1472 (1970).
[115] 29 U. S. C. § 651 (Sup. 1974).
[116] 29 U. S. C. §§ 658, 659 (Sup. 1974).
[117] 29 U. S. C. § 659 (Sup. 1974).
[118] 29 U. S. C. § 660 (Sup. 1974).
[119] 29 U. S. C. § 652(5) (Sup. 1974).
[120] 29 U. S. C. § 666(j) (Sup. 1974).
[121] 29 U. S. C. § 666 (Sup. 1974).
[122] 30 U. S. C. § 801 (1970).
[123] 30 U. S. C. § 818 (1970).
[124] 30 U. S. C. § 819 (1970).
[125] 30 U. S. C. § 819 (c) (1970).
[126] 15 U. S. C. § 1451 (1970).
[127] 15 U. S. C. § 1453 (1970).
[128] 15 U. S. C. § 1454 (1970).
[129] 15 U. S. C. § 1452 (1970).
[130] 15 U. S. C. § 45(b) (1970).
[131] 15 U. S. C. § 1456 (b) (1970).
[132] 15 U. S. C. § 1456 (a) (1970).
[133] 15 U. S. C. § 41 (1970).
[134] 15 U. S. C. § 45 (1970).
[135] 15 U. S. C. § 45 (b) (1970).
[136] 15 U. S. C. § 45 (c) (1970).
[137] 15 U. S. C. § 45 (l) (Sup. 1974).
[138] 15 U. S. C. § 52 (1970).
[139] 15 U. S. C. § 53 (1970).
[140] 15 U. S. C. § 54 (a) (1970).
[141] *Id.*

[The End]

Now Ready . . .

For Preparing 1974 Tax Returns

1975 U. S. MASTER TAX GUIDE

When you need fast, accurate answers to puzzling tax problems, you'll welcome this timely new 58th edition. Reflecting major and pertinent federal tax changes that affect 1974 returns, the GUIDE explains the basic rules concerning personal and business income tax.

Presenting a clear picture of current income taxes, the GUIDE offers clear-cut examples based on typical tax situations to show you how to handle special problems, protect against overpayments and mistakes. References to the Internal Revenue Code, the Regulations and the CCH Standard Federal Tax Reporter are included.

Special features are rate tables, tax calendar, state sales and gasoline tax deduction guides and check lists of taxable and nontaxable items, deductible and nondeductible items and depreciation tables. 544 pages, 5⅞" x 9", detailed topical index, heavy paper covers.

Order Your Copies Today!

The 1975 U. S. MASTER TAX GUIDE brings you top-flight tax help you're sure to welcome.

To order your copies now for prompt delivery, write Commerce Clearing House, Inc., 4020 W. Glenlake Ave., Chicago, Ill. 60646. Ask for *1975 U. S. Master Tax Guide* (5955) at the following prices: 1-4 copies, $7 ea.; 5-9, $6.50 ea.; 10-24, $5.90 ea.; 25-49, $5 ea. (To save postage, handling and billing charges, you may elect to send remittance with order. Include sales tax where required.) Pub. November 1974.

COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
4020 W. GLENLAKE AVE., CHICAGO, ILL. 60646

HARD BOUND EDITION

The 1975 U. S. MASTER TAX GUIDE is also available in a handsome, hard bound permanent edition (5885). Contents are identical to the paper-covered edition, but hard bound (two color, gold-stamped covers) for permanent reference. Pub. December 1974.

Price, $11 a copy.

(Subscribers for CCH's Standard Federal Tax Reports and Current Law Handybooks receive the paper covered edition of the 1975 U. S. Master Tax Guide. They should order only for extra copies or the hard bound edition.)

(198K/124)

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS OF TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
RETURN POSTAGE GUARANTEED

SECOND CLASS POSTAGE PAID
AT CHICAGO, ILLINOIS AND
AT ADDITIONAL MAILING OFFICES

FOOD DRUG COSMETIC LAW JOURNAL

ORDER FORM

MAIL TODAY!

CCH:

1. Rush . . . copies of 1975 U. S. MASTER TAX GUIDE (5955) at prices quoted below. (To save postage, handling and billing charges, you may elect to send remittance with order.)

1-4 copies $7.00 ea. 10-24 copies $5.90 ea.

5-9 copies $6.50 ea. 25-49 copies $5.00 ea.

2. Also send . . . . . copies of 1975 U. S. MASTER TAX GUIDE *Hard Bound Edition* (5885) at $11.00 per copy.

Send . . . Binders for the FOOD DRUG COSMETIC LAW JOURNAL at $6.00 each, with window labels for the following years:

. . . . . .

☐ Remittance herewith ☐ Send bill

INCLUDE SALES TAX WHERE REQUIRED

Signature . . . . . .

Firm . . . . . .

Attention . . . . . .

Street & Number . . . . . .

City & State . . . . . **Zip** . . . . .

(Subscribers for CCH's Standard Federal Tax Reports and Current Law Handybooks receive the paper-covered edition of the U. S. Master Tax Guide. They should order only for extra copies or the hard bound edition.)

Please Indicate Your CCH Account No.

. . . . . .

(5326) 5955—2057

BUSINESS REPLY MAIL

NO POSTAGE STAMP NECESSARY IF MAILED IN THE UNITED STATES

POSTAGE WILL BE PAID BY–

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS of TOPICAL LAW REPORTS

4020 W. GLENLAKE AVE.

CHICAGO, ILL. 60646

ORDER
CARD

MAIL TODAY!

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.